EXHIBIT 186

Highly Confidential - Subject to Further Confidentiality Review

```
 1        IN THE UNITED STATES DISTRICT COURT
           FOR THE NORTHERN DISTRICT OF OHIO
 2                 EASTERN DIVISION
                      -  -  -

 3

    IN RE:  NATIONAL        :   HON. DAN A.
 4  PRESCRIPTION OPIATE      :   POLSTER
    LITIGATION               :
 5                           :
    APPLIES TO ALL CASES     :   NO.
 6                           :   1:17-MD-2804
                             :
 7

 8           - HIGHLY CONFIDENTIAL -

    SUBJECT TO FURTHER CONFIDENTIALITY REVIEW
 9

10                   VOLUME II
11                    -  -  -
12                March 8, 2019
13                    -  -  -
14

15                Continued videotaped
    deposition of MICHELE R. DEMPSEY, taken
16  pursuant to notice, was held at the law
    offices of Drinker Biddle & Reath, 105
17  College Road East, Princeton, New Jersey,
    beginning at 10:15 a.m., on the above
18  date, before Michelle L. Gray, a
    Registered Professional Reporter,
19  Certified Shorthand Reporter, Certified
    Realtime Reporter, and Notary Public.
20

                      -  -  -

21

          GOLKOW LITIGATION SERVICES
22     877.370.3377 ph | 917.591.5672 fax
                deps@golkow.com
23

24
```

1   A.   This was at that time, yes.

2   Q.   Then I'm going to flip

3   forward to that separator sheet that I

4   spoke to you about, with the big bold

5   numbers for the separate set of Bates

6   numbering.

7   And there we have the Drug

8   and Chemical Advisory Group LLC,

9   suspicious orders monitoring, SOM, for

10   Johnson & Johnson, dated December 13,

11   2017. Presented by Terrance W.

12   Woodworth.

13   Do you see that?

14   A.   Yes.

15   Q.   Was this the presentation or

16   the slideshow of the presentation that

17   Mr. Woodworth presented to your

18   December 13th workshop on suspicious

19   order monitoring?

20   A.   Yes, it is.

21   Q.   It is. Okay. And it goes

22   through an overview of drug control

23   history; is that right? Is that a yes?

24   A.   Yes, yes.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   Okay. And we'll flip

2   through it fairly quickly for time

3   purposes.

4   And at Page 7, it addresses

5   U.S. drug law and regulations, Controlled

6   Substance Act, CSA, of 1970.

7   Do you see that?

8   A.   Yes, I do.

9   Q.   That Page 9, it's addressing

10   Schedule II through V drugs, which are

11   deemed, according to Mr. Woodworth, to

12   have a -- to include at Schedule II,

13   excuse me, hydromorphone, morphine,

14   fentanyl, methylphenidate.

15   Do you see that?

16   A.   Yes, I do.

17   Q.   And at Page 11,

18   Mr. Woodworth was addressing the opioid

19   epidemic in the U.S.; is that right?

20   A.   Yes, he was.

21   Q.   At Page 12, he was

22   addressing how in 2015 there were 52,404

23   drug-related overdose deaths; is that

24   right?

1   MR. BARKER: Object to form.

2   THE WITNESS: Yeah.

3   BY MR. JANUSH:

4   Q.   And he addressed there were

5   143 deaths every 24 hours; is that also

6   right?

7   MR. BARKER: Object to form.

8   THE WITNESS: That is the

9   data that he presented.

10 BY MR. JANUSH:

11   Q.   Okay. He presented data

12 that 33,091 deaths involved opioids

13 including heroin; is that also right?

14   MR. BARKER: Object to form.

15   THE WITNESS: That is what

16   is presented on the slide, yes.

17 BY MR. JANUSH:

18   Q.   And he went into a little

19 bit more detail about the -- on an

20 average day in the U.S., at Page 13, the

21 650,000 opioid prescriptions that are

22 dispensed; is that right?

23   MR. BARKER: Object to form.

24   THE WITNESS: The slide does

1   present the data on the opioid

2   prescriptions, yeah.

3 BY MR. JANUSH:

4   Q. And he addressed, at Page

5 14, opioid diversion and abuse and the

6 high abuse potential of these drugs; is

7 that right?

8   A. He did speak to high abuse

9 potential during the presentation.

10   Q. And he addressed severe

11 dependence liabilities as well, didn't

12 he?

13   A. He read the bullet during

14 his presentation, yes. He did. He

15 mentioned -- so these are the bullets

16 that he read during the training.

17   Q. Okay. At Page 17, he

18 addressed 21 C.F.R. 1301.74(b); is that

19 right?

20   A. Yes.

21   Q. And that says, "The

22 registrant shall design and operate a

23 system to disclose to the registrant

24 suspicious orders of controlled

1   substances. The registrant shall inform

2   the field division office of the

3   administration in his area of suspicious

4   orders when discovered by the

5   registrant."

6   Do you see that?

7   A.   Yes.

8   Q.   And do you recall this being

9   presented to Johnson & Johnson?

10   A.   Yes.

11   MR. BARKER: Object to form.

12   BY MR. JANUSH:

13   Q.   And then he defined the

14   suspicious order monitoring regulation or

15   quoted the definition at Page 18, or

16   Slide 18. Quote, "Suspicious orders

17   include orders of unusual size, orders

18   deviating substantially from a normal

19   pattern, and orders of unusual

20   frequency."

21   Do you see that?

22   A.   Yes, I do.

23   Q.   Did you have an

24   understanding that this was the

1 definition of suspicious orders?

2   A.   Yes, we did.

3   Q.   Okay. What's the earliest

4 date that you had that understanding of

5 this definition?

6   MR. BARKER: Object to form.

7   THE WITNESS: Back to my

8   early -- when I took over the DEA

9   compliance with Noramco in 2007,

10   2008.

11 BY MR. JANUSH:

12   Q.   So in or around 2007 or

13 2008, you had an understanding that the

14 definition of suspicious orders include

15 orders of unusual size, orders deviating

16 substantially from a normal pattern, and

17 orders of unusual frequency; is that

18 right?

19   A.   Yes.

20   Q.   We're going to move on from

21 this exhibit for a moment.

22   (Document marked for

23   identification as Exhibit

24   Janssen-Dempsey-24.)

Highly Confidential - Subject to Further Confidentiality Review

```
1    BY MR. JANUSH:

2         Q.    I'm going to mark a new

3    exhibit as Exhibit Dempsey -- Exhibit 24.

4              MR. JANUSH:  And copies to

5         opposing counsel.

6    BY MR. JANUSH:

7         Q.    This exhibit is

8    Bates-stamped JAN-MS-05444730.

9              It is an e-mail from Valerie

10   Chikwendu to Michele Dempsey.  And you

11   don't actually get the date until reading

12   slightly below the first e-mail.  And it

13   looks like it's June 8th, 2018.  Do I

14   have that right?

15        A.    Yes.

16        Q.    And who is Valerie

17   Chikwendu?

18        A.    She is a project manager

19   from the project management organization

20   of JOM.

21        Q.    And what does it mean to be

22   a project manager?

23        A.    You take on a project to

24   make sure you have the funding, the team,
```

1   the resources, the capital expenses to

2   deliver a project.

3   Q.   Does she work within a

4   different -- a specific group? For

5   example, does she work within compliance?

6   A.   No, she does not.

7   Q.   She does not. So she

8   assists in getting a project funded, off

9   the ground, et cetera; is that right?

10   A.   She does all the tactical

11   activity to facilitate making sure a

12   project gets done when it's supposed to

13   get done.

14   Q.   Okay. And she is providing

15   you with a draft e-mail, it looks like

16   to, a Sudha, S-U-D-H-A. Who is Sudha?

17   A.   I believe she's a finance

18   leader.

19   Q.   Okay. And in this draft

20   e-mail, she's addressing questions that

21   Sudha raised earlier in the e-mail string

22   regarding the compliance-related

23   investment to meet DEA requirements; is

24   that right?

1   A.   Can I read?

2   Q.   You may.

3   A.   Thank you.

4   Q.   It's the second page. Turn

5   to the -- follow with me, the second page

6   of the e-mail is where I'm focusing where

7   Sudha wrote in the middle of the page to

8   John Dzurenko, Katrina Purifoy -- or

9   Purifoy, and is addressing, "Agree that

10   it is compliance related. Would like to

11   understand how this investment will meet

12   the DEA requirement. Are there other

13   programs that are doing this, i.e.,

14   within commercial? What is the

15   cap/expense split?"

16   Do you see that?

17   A.   Yes, I do.

18   Q.   Okay. And Valerie Chikwendu

19   is drafting a response for you and she

20   wrote on Page 1, "Michele, here's the

21   e-mail I plan to send."

22   Do you see that?

23   A.   Yes, I do.

24   Q.   All right. And I'm moving

Highly Confidential - Subject to Further Confidentiality Review

1   down to the draft e-mail. She wrote,

2   "Hello, Sudha. Here are the answers to

3   your questions below. I have also cc'd

4   Michele Dempsey, director of controlled

5   substances compliance, for further

6   elaboration if needed.

7   "DEA guidelines: The DEA

8   guidelines include an expectation for us

9   to flag: Orders of unusual size, orders

10   deviating substantially from normal

11   pattern, orders of unusual frequency."

12   Do you see that?

13   A.   Yes, I do.

14   Q.   Okay. Now, focusing on my

15   prior question, Ms. Dempsey, that I asked

16   just moments ago, I asked if you agreed

17   with that definition. And if -- you said

18   you did, right?

19   A.   Yes.

20   Q.   I asked when is your

21   earlier -- earliest understanding of that

22   definition, and you said around 2007,

23   2008 when you joined Noramco; is that

24   right?

1   A.   Yes.

2   Q.   Okay. Next sentence in this

3   draft e-mail is, "We currently have a

4   process to flag unusual based on List 1

5   chemicals, and it is not up to current

6   industry practice. The other two

7   requirements are vulnerabilities that

8   must be addressed. Our current

9   monitoring program flags orders of

10   unusual size (a running average of past

11   orders is taken and we flag any order

12   that is 300 percent more than average).

13   We do not currently account for ordering

14   frequency or cumulative effect of

15   multiple orders in one month against the

16   threshold, and we plan to incorporate

17   other ordering deviations based on

18   patterns which will be defined as part of

19   this project."

20   Did I read that correctly?

21   A.   You did.

22   Q.   Do you agree that at that

23   time, the we, Johnson & Johnson, or JOM,

24   did not account with its current

1   monitoring system, for ordering frequency

2   or cumulative effect of multiple orders

3   in one month against a threshold?

4   A.   No.

5   Q.   You don't agree or you do

6   agree?

7   A.   I do not agree. The

8   algorithm, which is what is being spoken

9   to, because we're asking for capital

10   funding to reprogram, to come up with an

11   algorithm that factors in the three, the

12   current one was only looking at the

13   12-month rolling average of a quantity.

14   But our program, the

15   outside, the overall review and

16   investigation, that's where we have the

17   frequency and pattern reviewed, because

18   if a customer orders one SKU every

19   12 months, it's going to be flagged. And

20   then we look at the ordering pattern,

21   their history, and that's how -- so this

22   was for a capital appropriation to get

23   funding for an IT system.

24   Q.   Let's go back to what this

1   says, because -- because you had an

2   opportunity to edit this document, right?

3   Let's go up to the top of the e-mail.

4   A.   Yes.

5   Q.   It says -- I'm going to

6   circle it.

7   "Made some tweaks below.

8   Thank you."

9   Do you see that?

10   A.   Yes. Yes.

11   Q.   Your tweaks are embedded in

12   this document, correct, in this e-mail?

13   "Made some tweaks below"?

14   A.   Yes.

15   MR. BARKER: Object to form.

16   BY MR. JANUSH:

17   Q.   Is that right?

18   A.   I did make some

19   modifications below.

20   Q.   Okay. Okay. And you didn't

21   edit the language, "We currently have a

22   process to flag unusual based on List 1

23   chemicals and is not up to current

24   industry practice."

Highly Confidential - Subject to Further Confidentiality Review

1   You didn't edit that

2   sentence, right?

3   A.   No, I -- I don't have her

4   previous one to see what she originally

5   wrote to see what I actually tweaked.

6   Q.   But you didn't change it?

7   A.   No.

8   Q.   That language is in here,

9   you didn't modify that beyond the

10   statement that's written here, correct?

11   A.   Right. Our algorithm --

12   Q.   No, that's not what I'm

13   asking you. I'm -- don't talk about your

14   algorithm. I'm asking about whether you

15   modified that first sentence, beyond

16   what's written here?

17   A.   No, I didn't.

18   MR. BARKER: Object to form.

19   BY MR. JANUSH:

20   Q.   No, you did not, right?

21   A.   No, I not modify it.

22   Q.   Second sentence, "The other

23   two requirements are vulnerabilities that

24   must be addressed."

1   You didn't modify that

2   sentence beyond the language that's

3   written there, correct?

4   MR. BARKER: Object to form.

5   THE WITNESS: No, I didn't.

6   BY MR. JANUSH:

7   Q.   Third sentence, "Our current

8   monitoring program flags orders of

9   unusual size, a running average of past

10 orders is taken, and we flag any order

11 that is 300 percent more than average."

12   You didn't modify that

13 sentence beyond what's written there,

14 right?

15   A.   No, I didn't.

16   Q.   Next sentence, "We do not

17 currently account for ordering frequency

18 or cumulative effect of multiple orders

19 in one month against a threshold, and we

20 plan to incorporate other ordering

21 deviations based on patterns which will

22 be defined as part of the project."

23   You didn't edit this

24 sentence beyond what is written here; is

1   that right?

2   MR. BARKER: Object to form.

3   THE WITNESS: I don't have

4   the original to see what I

5   actually tweaked. But this is the

6   end product which would include

7   what I tweaked.

8   BY MR. JANUSH:

9   Q.   Thank you. Now, to go back

10   to what you were addressing earlier, I

11   think. Your algorithm was designed to

12   flag any order that is 300 percent more

13   than the average rolling annual weekly

14   order; is that right?

15   A.   For every customer that

16   places an order for one particular SKU,

17   it looks at the 52-week history ordering

18   and compares -- takes an average, times

19   by the 300 percent, and compares the

20   current order against what they have

21   ordered -- this threshold.

22   Q.   And by this threshold, you

23   mean the 300 percent more than their

24   average; is that right?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   Yes.

2   Q.   I'm going to move on to

3   another document that I'm marking as

4   Dempsey Exhibit 25.

5   (Document marked for

6   identification as Exhibit

7   Janssen-Dempsey-25.)

8   MR. JANUSH: Let me hand all

9   three to you.

10   BY MR. JANUSH:

11   Q.   This document is

12   Bates-stamped in the upper right corner

13   vertically, JAN-MS-02960650. It's a

14   completed questionnaire from Miami-Luken

15   concerning the JOM SOM program

16   questionnaire.

17   Does that look right to you

18   on the first page, that this would have

19   been the JOM program -- SOM program

20   questionnaire?

21   MR. BARKER: Object to form.

22   THE WITNESS: It appears to

23   be the April 2014 questionnaire.

24

Highly Confidential - Subject to Further Confidentiality Review

1   BY MR. JANUSH:

2   Q.   Okay. And I've only

3   encompassed this large 70-page document

4   for your review because it included a

5   letter from the DEA way at the end of

6   this, at Bates number ending in 712. So

7   I'm going to ask you to turn to -- look

8   in the upper right corner and turn to

9   712.

10   You are with me on 712. The

11   header is -- the letterhead is from the

12   United States Department of Justice Drug

13   Enforcement Administration.

14   Do you see that?

15   A.   Mm-hmm.

16   Q.   The date is December 27,

17   2007.

18   Do you see that?

19   A.   Mm-hmm.

20   Q.   And it's signed by, if you

21   turn to Page 2, Joseph T. Rannazzisi,

22   deputy assistant administrator, office of

23   diversion control.

24   Do you see that?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   Yes, I do.

2   Q.   Okay. So I'm producing you

3   with the letter that was produced from

4   Miami-Luken as part of their

5   questionnaire response on your suspicious

6   order monitoring questionnaire because

7   I'm representing to you today that we

8   couldn't locate the Johnson & Johnson,

9   JOM, Noramco, or Ortho-McNeil letter that

10   might have been sent by the -- that would

11   have been sent, excuse me, by the United

12   States Department of Justice.

13   I'm going to read you the

14   first sentence. It says, "Dear

15   Registrant, this letter is being sent to

16   every entity in the United States

17   registered with the Drug Enforcement

18   Administration, DEA, to manufacture or

19   distribute controlled substances. The

20   purpose of this letter is to reiterate

21   the responsibilities of controlled

22   substance manufacturers and distributors

23   to inform DEA of suspicious orders in

24   accordance with 21 C.F.R. 1301.74(b)."

1   Do you see that?

2   MR. BARKER: Object to form.

3   Object to the preamble.

4   THE WITNESS: Yes, I do see

5   it.

6   BY MR. JANUSH:

7   Q.   And in December of 2007,

8   Janssen was a manufacturer of controlled

9   substances, correct?

10   A.   Yes.

11   Q.   And go on to read the next

12   paragraph. "In addition to and not in

13   lieu of the general requirement under 21

14   U.S.C. 823, that manufacturers and

15   distributors maintain effective controls

16   against diversion, DEA regulations

17   require all manufacturers and

18   distributors to report suspicious orders

19   of controlled substances."

20   Did I read that right?

21   MR. BARKER: Object to form.

22   THE WITNESS: Yes, you did.

23   BY MR. JANUSH:

24   Q.   Okay. Title 21 C.F.R.

1   1301.74(b) specifically requires that a

2   registrant design and operate a system to

3   disclose to the registrant suspicious

4   orders of controlled substances."

5   Did I read that correctly?

6   MR. BARKER: Object to form.

7   THE WITNESS: Yes.

8   BY MR. JANUSH:

9   Q.   Okay. I'm going to have

10   you, for the purposes of time, jump down

11   to the very last paragraph on the page

12   with me. Okay.

13   It begins with, "The

14   regulation." Are you there?

15   A.   Yes.

16   Q.   Okay. I'm going to read it

17   out loud.

18   "The regulation specifically

19   states that suspicious orders include

20   orders of an unusual size, orders

21   deviating substantially from a normal

22   pattern, and orders of an unusual

23   frequency."

24   Do you see that?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   Yes.

2   MR. BARKER: Object to form.

3   BY MR. JANUSH:

4   Q.   And that's the same language

5   that Terrance Woodworth presented to you

6   on December 13, 2017, in his suspicious

7   order monitoring workshop, right?

8   A.   Very similar wording.

9   Q.   Okay. And it's the same

10   language that, in the e-mail below, in

11   the e-mail that we just marked into

12   evidence at Exhibit 24 that I

13   highlighted -- we'll pull that up on the

14   screen for you. It's the same language

15   that is listed in this June 8, 2018,

16   e-mail that you had the opportunity to

17   edit concerning, "The DEA guidelines

18   include an expectation for us to flag

19   orders of unusual size, orders deviating

20   substantially from normal pattern, orders

21   of unusual frequency."

22   Is that right?

23   A.   Yes.

24   Q.   Same language?

1   A.   Yes.

2   Q.   So the requirements that

3   Joseph Rannazzisi, as the deputy

4   assistant administrator, office of

5   diversion control, was listing in 2007

6   are the same requirements that you and

7   your company were acknowledging in

8   June 2018 that you had only met one of

9   the three requirements with your

10 algorithm, correct?

11   A.   Our algorithm was only

12 addressing the quantity. But our program

13 outside the algorithm covered the other

14 aspects. But we wanted --

15   MR. JANUSH: Move to strike.

16   Nonresponsive.

17 BY MR. JANUSH:

18   Q.   I didn't ask about your

19 program. For the moment, I asked only

20 about your algorithm. So --

21   A.   But the regulation doesn't

22 say the algorithm has to have all three.

23 It just says that you have to have a

24 system.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   Right. I asked about your

2   algorithm, did I not?

3   A.   Yes.

4   Q.   Okay. And there's a reason

5   for me asking that. I'm going to connect

6   the dots in a moment. Okay?

7   A.   Okay.

8   Q.   So my question was, you were

9   acknowledging in that e-mail, Exhibit 24,

10   that your algorithm only addressed one of

11   the three requirements stated by the DEA

12   concerning unusual size, deviating

13   substantially from a normal pattern, and

14   orders of an unusual frequency; is that

15   right?

16   MR. BARKER: Object to form.

17   BY MR. JANUSH:

18   Q.   I'm only speaking of the

19   algorithm.

20   A.   That is what I -- what is

21   written.

22   Q.   Okay. And in realtime, in

23   practice, when an order is placed for a

24   Schedule II drug, it is your algorithm

Highly Confidential - Subject to Further Confidentiality Review

1   that will flag whether the order is

2   suspicious or atypical and needing review

3   in that moment; isn't that right?

4   MR. BARKER: Object to form.

5   THE WITNESS: When an order

6   is placed and the quantity doesn't

7   match what the weekly average of a

8   52 weeks times three, it gets

9   flagged.

10   BY MR. JANUSH:

11   Q.   Right. So going back to the

12   question I asked you. In realtime, in

13   practice, when an order is placed for a

14   Schedule II drug, it is your algorithm

15   that will flag whether the order is

16   suspicious or atypical and needing review

17   in that moment, true or false?

18   A.   True.

19   Q.   Okay. So the fact that you

20   have a program that has the capability to

21   analyze orders beyond the algorithm only

22   comes into play when that -- on that date

23   the order is placed when an order is

24   flagged; isn't that right?

Highly Confidential - Subject to Further Confidentiality Review

```
1              MR. BARKER:  Object to form.

2              THE WITNESS:  When the order

3         is flagged as atypical, it gets

4         investigated.  And then that

5         includes running all of the

6         historical -- looking through the

7         ordering pattern, as well as the

8         frequency part of that.

9    BY MR. JANUSH:

10        Q.    But you can't do an

11   investigation until the order is flagged,

12   right, in realtime?

13        A.    Agreed.

14        Q.    Okay.  When we concluded the

15   deposition -- when we concluded your

16   first day of this deposition, we ended

17   discussing the audit and that

18   December 13, 2017, workshop by the drug

19   and chemical advisory group, as we

20   discussed earlier, right?

21        A.    Yes.

22             (Document marked for

23        identification as Exhibit

24        Janssen-Dempsey-26.)
```

1   BY MR. JANUSH:

2   Q.   Here's Exhibit 26.

3   MR. JANUSH: There are

4   copies for counsel.

5   BY MR. JANUSH:

6   Q.   This has been produced by

7   your counsel following the January 21 --

8   22, excuse me, 2019, Day 1 of your

9   deposition.

10   And this document appears to

11   be the draft presented to Johnson &

12   Johnson by Terrance Woodworth dated

13   January 8, 2018; is that right?

14   A.   Yes.

15   Q.   And the purpose of this is

16   found within the title. It's an

17   evaluation of the suspicious orders

18   monitoring system for Johnson & Johnson;

19   is that right?

20   A.   Yes.

21   Q.   Okay. And Terrance met with

22   you and key customer service personnel at

23   the Piscataway facility concerning their

24   roles in the operation of the JOM

Highly Confidential - Subject to Further Confidentiality Review

1   suspicious order monitoring program in

2   order to conduct his examination of your

3   system, his audit of your system; is that

4   right?

5   A.   He met with several groups

6   to discuss the current process, yes.

7   Q.   Okay. And for the record,

8   if I didn't already say this, this

9   document starts at JAN-MS-05444748.

10   I'm going to have you jump

11   to Page 3. We're just going to focus on

12   some key aspects of this document. At

13   Paragraph 3 at the bottom of the page,

14   Terrance wrote, "Start resolving the

15   issue of possibly not applying the SOM

16   order quantity assessment algorithm (SOM

17   algorithm) to all customer orders for

18   Schedule III and IV controlled substances

19   which are received via electronic data

20   interchange (EDI) throughout the day and

21   night.

22   "The SOM algorithm is run

23   against all existing controlled

24   substances orders each day at 3:45 p.m.

Highly Confidential - Subject to Further Confidentiality Review

1   Any orders that are received by J&J

2   customer service via EDI after that time

3   may be shipped to a customer the

4   following day without being subjected to

5   the SOM algorithm unless the EDI orders

6   are checked the next morning to ensure

7   the SOM algorithm has been applied."

8   Do you see that?

9   A.   Yes.

10   Q.   And we addressed that, you

11   may recall, at Day 1 of your deposition,

12   this issue of -- the fact that your

13   monitoring system physically cuts off at

14   a certain point in the afternoon and

15   would require manual review the next

16   morning to ensure that controlled

17   substance orders do not go out unchecked.

18   Do you remember that?

19   MR. BARKER: Object to form.

20   THE WITNESS: Yes.

21   BY MR. JANUSH:

22   Q.   Okay. This issue, was it

23   new to you following the audit or did you

24   know about this limitation, this time

1   limitation concerning when the system

2   would shut down in the late afternoon?

3   MR. BARKER: Object to form.

4   THE WITNESS: We knew that

5   the program ran every day in the

6   afternoon. And that's why it was

7   important -- when orders are

8   received, they get manually

9   entered and placed in business

10   manager hold until this program is

11   run.

12   And then the morning, the

13   timestamp for every order is

14   compared to make sure that the

15   order is placed before the report

16   is run.

17   BY MR. JANUSH:

18   Q.   And then I'm going to jump

19   down to Paragraph 7. It says, "Consider

20   modifying" -- same page, same page,

21   sorry.

22   "Consider modifying

23   Janssen's corporate policy to include the

24   organization's responsibility for

Highly Confidential - Subject to Further Confidentiality Review

1   safeguarding controlled substances and

2   preventing their diversion, maintenance

3   of effective controls to prevent

4   diversion, Title 21 United States Code

5   Section 823, and include a summary of the

6   SOM program."

7   Do you see that?

8   A.   Mm-hmm.

9   Q.   Who -- what was being

10   referred to here concerning modifying --

11   consider modifying Janssen's corporate

12   policy to include the organization's

13   responsibility for safeguarding

14   controlled substances and preventing

15   their diversion?

16   A.   A lot of the manufacturing

17   sites had a diversion control policy.

18   And they wanted to make sure that that

19   diversion control policy incorporated the

20   suspicious order monitoring requirements.

21   Q.   Okay. And at Page 8,

22   Paragraph 8, he noted, "Stop using the

23   term 'suspicious' or 'unusual' in all

24   standard operating procedures and work

Highly Confidential - Subject to Further Confidentiality Review

1   instructions related to the corporation's

2   SOM program and start using another term

3   which is more appropriate" -- "a more

4   appropriate characterization of the order

5   evaluation possess, such as 'questionable

6   orders' or 'atypical orders' or 'orders

7   of concern.'"

8   Do you see that?

9   A.   Yes, I do.

10   Q.   And after receiving his

11   guidance, you all actually did stop using

12   the term "suspicious" and modified, your

13   standard operating procedures, to

14   language such as "atypical orders," or

15   "questionable orders"; isn't that right?

16   A.   We started to use

17   questionable orders.

18   Q.   Okay. And here too in the

19   original audit, the original draft of the

20   audit, Terrance Woodworth -- I'm going to

21   circle the center. I've already

22   highlighted it -- is addressing the

23   registrant's obligation to design and

24   operate a system to disclose to the

 1   registrant suspicious orders of

 2   controlled substances.

 3   And Terrance quoted, "The

 4   registrant shall inform the field

 5   division office of the administration in

 6   his area of suspicious orders when

 7   discovered by the registrant. Suspicious

 8   orders include orders of unusual size,

 9   orders deviating substantially from a

10   normal pattern, and orders of unusual

11   frequency."

12   Do you see that?

13   A.   Yes, I do.

14   Q.   And that's what we've been

15   discussing, those three factors; is that

16   right?

17   A.   Yes.

18   Q.   Okay. And then if you move

19   to Page 8, your auditor addressed, in the

20   middle of the page, second paragraph --

21   I'm going to show you on your screen

22   where I am with the big vertical line

23   that I'm highlighting, okay, vertical

24   lines.

1   "The JOM program also takes

2   advantage of the capabilities of the SAP

3   software, which enables generation of

4   several key reports that are helpful in

5   identifying questionable aspects of an

6   order or customer activity over selected

7   time periods."

8   Do you see that?

9   A.   Yes, I do.

10   Q.   And then it goes on to say,

11   in the second sentence, "For example,

12   among many other possible reports, the

13   system can facilitate a report of all

14   controlled substance orders where the DEA

15   registration is missing, invalid or

16   expired; all controlled substances orders

17   where there is an incomplete or

18   inaccurately completed DEA Form 222; and

19   all monitored orders for controlled

20   substances where the quantity ordered has

21   exceeded the current threshold

22   algorithm."

23   Do you see that?

24   A.   Yes, I do.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   And so that means that the

2   program looks at monitored orders where

3   the quantity order exceeded the then

4   current 300 percent of an average annual

5   weekly order; is that right?

6   MR. BARKER: Object to form.

7   THE WITNESS: The algorithm

8   has the current threshold for

9   quantity ordered.

10   BY MR. JANUSH:

11   Q.   So is that right what I

12   asked?

13   A.   Yes.

14   Q.   And then he appears to be

15   addressing, in the last paragraph, that,

16   "Currently it appears the JOM

17   distribution center in Kentucky is unable

18   to independently render a final SOM

19   determination on a given atypical order.

20   Several different company elements, such

21   as customer service, channel operations,

22   established products, supply chain

23   analysis, and quality assurance, possess

24   information and perform key functions

1   which could pertain to every controlled

2   substance order."

3   Do you see that?

4   A.   Yes.

5   Q.   Okay. So was he getting at

6   the point that the Kentucky distribution

7   center could not independently render a

8   final suspicious order monitoring

9   determination because several other

10   company functions like customer service

11   and channel operations had to play a role

12   in the determination of a suspicious

13   order?

14   A.   I think what he was talking

15   about is, physically in Kentucky, we only

16   have the material handlers, and that all

17   of the customer service, compliance, and

18   the planners are located in New Jersey.

19   Q.   I think we're on the same

20   page. That was --

21   A.   Right.

22   Q.   That was what I was getting

23   at with my question.

24   A.   But the order -- the order

1   is not released to pick, pack, and

2   deliver until all the elements are

3   reviewed. And that releasing happens

4   in -- by customer service, not local.

5   Q.   Then on Page 9, he addresses

6   recommendations. I'm not going to go

7   through every one for the purpose of

8   time.

9   I am going to start with the

10   bottom of Page 9 at Paragraph 3. He does

11   address that you have to start resolving

12   the issue of possibly not applying the

13   SOM order quantity assessment algorithm

14   to all customer orders for Schedule III

15   and IV controlled substances which are

16   received via electronic data interchange

17   throughout the day and night, right?

18   A.   Yes.

19   Q.   But there's actually no

20   difference between a Schedule II order

21   and a Schedule III and IV order with

22   respect to how that algorithm ran and

23   when that algorithm cut off during the

24   day; isn't that right?

Highly Confidential - Subject to Further Confidentiality Review

1   MR. BARKER: Object to form.

2   THE WITNESS: Well, Schedule

3   IIs don't come in through EDI.

4   BY MR. JANUSH:

5   Q.   Oh, right.

6   A.   Schedule II have 222s that

7   have to be entered in.

8   Q.   That's right. And once

9   entered in, how do they -- how do they

10   run?

11   A.   Well, when you receive the

12   order, it goes into SAP and placed on

13   business manager hold until the

14   algorithm --

15   Q.   Right. So the same

16   algorithm, though, applies with these

17   Schedule II as well, is what I'm getting

18   at, right?

19   A.   Yes.

20   Q.   And the same cutoff of that

21   algorithm, in terms of when it runs, it

22   runs for II, III, and IV, and it stops at

23   3:45 in the afternoon; is that right?

24   MR. BARKER: Object to form.

Highly Confidential - Subject to Further Confidentiality Review

```
 1              THE WITNESS:  It runs --

 2        yes, it runs every afternoon.

 3   BY MR. JANUSH:

 4        Q.    And stops after that 3:45

 5   run, correct?

 6              MR. BARKER:  Object to form.

 7              THE WITNESS:  It takes every

 8        order that's been placed up until

 9        the time it runs and it runs all

10        those orders through the

11        algorithm.

12   BY MR. JANUSH:

13        Q.    Right.  And that includes

14   Schedule II, correct?

15        A.    Yes.

16        Q.    Now let's go to Paragraph 4,

17   okay?

18              "Start modifying the

19   existing suspicious order monitoring

20   algorithm and/or adding algorithms to

21   include additional evaluation criteria

22   for each specific DEA basic class of

23   controlled substance handled by J&J;

24   example fentanyl, methylphenidate, and
```

1   tramadol."

2   Do you see that?

3   A.   Yes.

4   Q.   "Consider a base unit

5   measurement" -- "unit of measurement such

6   as grams of active ingredient for the SOM

7   algorithms.

8   "Consider separating J&J

9   customers into two or more groups and

10   perform different analyses of orders for

11   these different groups; e.g., largest

12   three wholesalers in one group, smaller

13   wholesalers in another group.

14   "Consider evaluating

15   customer orders for specific DEA basic

16   classes of substances against similar

17   size and geographically placed customers,

18   and perform national, regional, state,

19   and perhaps three digit zip code

20   comparisons among like-size customers."

21   Did I read that correctly?

22   A.   Yes, you did.

23   Q.   Before getting Terrance

24   Woodworth's audit suggestion within this

Highly Confidential - Subject to Further Confidentiality Review

1   report concerning this Paragraph 4, had

2   you and your team previously considered

3   modifying your suspicious order

4   monitoring algorithm in the manners that

5   he suggested here?

6   A.   We were in discussion about

7   these items. After -- through

8   benchmarking, in recent benchmarking, we

9   realized these are potential enhancements

10   that DEA may expect us to do.

11   Q.   And let's go to Paragraph

12   4A.

13   Quote, "Stop using the

14   current single-criterion algorithm which

15   selects and holds orders from customers

16   when the quantity of an order is greater

17   than three times, 300 percent, the

18   customer's average weekly order based on

19   a rolling 12-month ordering history from

20   that customer."

21   Do you see that?

22   A.   Yes, I do.

23   Q.   And this is -- this report

24   was dated January --

Highly Confidential - Subject to Further Confidentiality Review

1   A.   January.

2   Q.   -- of -- January 6th -- 8th,

3   excuse me, of 2018, right?

4   A.   Yes.

5   Q.   And a little more than a

6   year and about two weeks -- actually a

7   year and exactly two weeks later, on

8   January 22, 2019, I first deposed you.

9   And you indicated that you had not

10   stopped using the single-criterion

11   algorithm as of that date and were still

12   using the 300 percent of the customer's

13   average weekly order in J&J's suspicious

14   order monitoring algorithm; is that

15   right?

16   MR. BARKER: Object to form.

17   THE WITNESS: We are

18   currently using the algorithm

19   while the project, which you

20   already provided information on,

21   is underway.

22   BY MR. JANUSH:

23   Q.   And Terrance goes on to

24   critique the current single-criterion

1   algorithm, which, by the way -- we

2   established in the last deposition, and

3   just to refresh everything for Day 2,

4   this 300 percent of the customer's

5   average weekly order based on a rolling

6   12-month order history is the algorithm

7   that existed since the inception of

8   Johnson & Johnson's suspicious order

9   monitoring program through the present

10   date, right?

11   MR. BARKER: Object to form.

12   THE WITNESS: This is the

13   algorithm that was implemented

14   late 2006.

15   BY MR. JANUSH:

16   Q.   Through the present date,

17   correct?

18   A.   Yes.

19   Q.   Okay. And Terrance

20   Woodworth states, "This algorithm only

21   measures quantity and does not consider

22   frequency or a pattern of ordering by the

23   same customer," right?

24   A.   Yes.

1   Q.   And you agree with that,

2   right?

3   MR. BARKER: Object to form.

4   THE WITNESS: It focuses on

5   the ordering of one single

6   customer, yes.

7   BY MR. JANUSH:

8   Q.   And that's not my question.

9   I said this algorithm only measures

10 quantity and does not consider frequency

11 or a pattern of ordering by the same

12 customer.

13   Do you agree with that?

14   A.   That is what the algorithm

15 does, the quantity.

16   Q.   And so you agree with that,

17 right? Yes?

18   A.   Yes.

19   Q.   And the algorithm compares a

20 customer's order quantity against only

21 that customer's average annual purchases,

22 right?

23   A.   Yes.

24   Q.   The algorithm would not

Highly Confidential - Subject to Further Confidentiality Review

1   detect multiple customer orders during a

2   given week, right?

3   MR. BARKER: Object to form.

4   THE WITNESS: Yes.

5   BY MR. JANUSH:

6   Q.   The algorithm would not

7   detect orders which consist of gradual

8   quantity increases of controlled

9   substance over time, right?

10   MR. BARKER: Object to form.

11   THE WITNESS: That is what

12   he wrote.

13   BY MR. JANUSH:

14   Q.   Is that right though?

15   A.   I've never seen it happen,

16   but it -- I guess it could.

17   Q.   Is it right that --

18   A.   He wrote that, yes. He

19   wrote that, yes.

20   Q.   I'm not asking if he wrote

21   it. I'm asking if you agree with it,

22   that the algorithm would not detect

23   orders which consist of gradual quantity

24   increases of a controlled substance over

1   time.

2   A.   In theory it could happen.

3   Q.   What could happen?

4   A.   That if they ordered tiny

5   increases over time, by averaging it out,

6   it might -- it might not show.

7   Q.   Meaning the algorithm might

8   not pick it up?

9   A.   Yes.

10   Q.   Okay. The algorithm would

11   not detect a new customer's orders for

12   controlled substances which initially

13   commence with larger than normal

14   quantities and remain at a constant

15   level.

16   Do you agree with that?

17   MR. BARKER: Object to form.

18   THE WITNESS: The algorithm

19   only detects what the orders are.

20   However, our outside processes by

21   onboarding new customers, we look

22   at their quantity. So, if -- so

23   what number gets entered into the

24   algorithm, I question that one,

1   that, you know, would we really

2   start a customer at a high level.

3   BY MR. JANUSH:

4   Q.   Well, you would go through

5   your -- your questionnaire process,

6   right?

7   A.   Yes.

8   Q.   And you would get on the

9   phone with the customer and ask what

10   their needs are, right?

11   A.   And then we would also

12   evaluate whether that makes sense.

13   Q.   Right. And if it seemed to

14   make sense to customer service to clear

15   the order, and the order started at a

16   high number, that would be the starting

17   point for that new customer, right?

18   A.   But customer service doesn't

19   do the approval. It would go to the DEA

20   compliance group that would look at it

21   and question it and ask for justification

22   for that high level.

23   Q.   Okay. So you -- you

24   corrected me in terms of the department

1   that would analyze it. But I'm still

2   addressing the fundamental concept. And

3   the fundamental concept that I'm

4   addressing is that DEA compliance would

5   question and speak with the customer and

6   see if they are content with the

7   explanation that the high order is

8   justified; is that correct?

9   A.   Yes. And with the

10   documentation on hand, yes, that could

11   happen.

12   Q.   And so once a customer

13   starts at a high, larger than normal,

14   quantity, if they remain at that constant

15   level, the algorithm wouldn't detect --

16   it wouldn't detect anything, right?

17   MR. BARKER: Object to form.

18   THE WITNESS: If they

19   consistent -- if they ordered

20   consistently that amount over

21   time. But if they had one big

22   order and they don't order for

23   12 months, the algorithm will flag

24   it. And we'll have to investigate

1   it again. Why did you not order

2   it, so --

3   MR. JANUSH: Move to strike

4   as nonresponsive.

5   BY MR. JANUSH:

6   Q.   The algorithm does not

7   distinguish between controlled

8   substances, geographic areas, or similar

9   size customers; example, similar size

10   wholesaler.

11   Do you agree with that?

12   A.   Our algorithm doesn't,

13   right.

14   Q.   Doesn't or does?

15   A.   Does not.

16   Q.   I'm going to have you turn

17   to Page 14, if you will.

18   At the top, I'm looking at

19   the bullets that fall within Terrance

20   Woodworth's Paragraph 12.

21   And to be fair, we'll go to

22   13 -- Page 13. He's addressing

23   continue -- issues to continue/enhance

24   J&J's program. And multiple bullets

1   follow.

2   And so on 14, I'm looking at

3   the second bullet. "When an SOM-related

4   action against a DEA registrant is noted,

5   determine whether there is a learning

6   from that case. Determining whether it

7   involves one of J&J's customers, and if

8   so, whether the JOM suspicious order

9   monitoring algorithm identified any

10   previous atypical orders for that

11   customer and modify the algorithm

12   accordingly."

13   Do you see that?

14   A.   Yes, I do.

15   Q.   Okay. And the last bullet

16   addresses, "Take past order examples and

17   evaluate their circumstances, order

18   patterns, and activity against revised

19   algorithm or algorithms to determine

20   discrepancies or adjustments needed."

21   Do you see that last bullet?

22   A.   Yes.

23   Q.   You didn't like that much,

24   did you?

Highly Confidential - Subject to Further Confidentiality Review

1   MR. BARKER: Object to form.

2   THE WITNESS: I don't

3   understand that. He was saying

4   that once we include his

5   enhancements, to keep looking

6   at -- he was asking us, once we

7   identify -- we fix the

8   algorithm -- not fix -- we make

9   these enhancements for quantity,

10   frequency, and pattern, he said we

11   should run past examples through

12   it.

13   And at this time we didn't

14   understand why, because the

15   algorithm, the thresholds we

16   already are setting up is based on

17   historical ordering pattern. And

18   those orders have already been

19   investigated.

20   And, you know, by sending

21   them through the new thresholds,

22   it would have confirmed we

23   shouldn't have investigated them,

24   because they were -- our current

Highly Confidential - Subject to Further Confidentiality Review

```
 1              algorithm was overflagging.

 2                   Do you know what I mean?

 3              Because we were going based on

 4              SKU, with these enhancements where

 5              we're going on active ingredient,

 6              if we were to throw all those

 7              orders through the new system,

 8              they would have shown that we

 9              shouldn't have investigated them.

10              And --

11    BY MR. JANUSH:

12         Q.   So you're saying -- saying

13    throwing orders into a more robust

14    algorithm would have shown you that you

15    shouldn't have investigated prior orders?

16    That's your position?

17         A.   No.

18         Q.   Okay.  So let's get this

19    straight so that I can explain my

20    question.

21         A.   All right.

22         Q.   As of this date that he,

23    Terrance, is making his recommendations,

24    you have a one-dimensional algorithm that
```

1   only looks at quantity ordered over the

2   past year, correct?

3   MR. BARKER: Object to form.

4   THE WITNESS: SKU ordered

5   over the year.

6   BY MR. JANUSH:

7   Q.   Right. Only looks at the

8   SKU of a given order, meaning the same

9   NDC code, the same drug at the same

10   milligram compared to that same drug at

11   the same milligram purchased over the

12   year, right?

13   A.   So, yeah. So --

14   Q.   And he's saying take past

15   order examples and evaluate them against

16   when you come up with whatever your new

17   future state algorithm is, isn't he?

18   A.   He is saying once we

19   incorporate the enhancements and we go to

20   active ingredient, so all of

21   methylphenidate a customer orders, run

22   these past orders through it.

23   Q.   And you expect less hits to

24   result under a newer program?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   Yes.

2   Q.   And why is that?

3   A.   Because we are currently

4   over flagging a lot because if a

5   customer -- we're basing it -- I can use

6   ADHD medicines. You know, 18-milligram

7   is not commonly prescribed. So a

8   customer may only order it once a year,

9   like in September before school starts.

10 And they only order that one 18-milligram

11 once a year.

12   But 12 months prior average

13 is zero. So we're going to flag it even

14 though it makes sense, if you run the

15 investigation, you run what they've

16 ordered the past year, or we actually go

17 back two years, they see this wholesaler

18 always gets this 18-milligram before

19 school starts.

20   Q.   You're only looking at the

21 outlier where a rare order or a lesser

22 ordered product is being placed. What

23 about the scenario where a Cardinal, for

24 example, is ordering a thousand cases of

1   Nucynta every few days or 600 cases of

2   Nucynta every few days in various

3   milligrams, and your old order would have

4   only been looking -- your old algorithm

5   would have only been looking at it as SKU

6   to SKU, and your new algorithm might be

7   looking at it in the cumulative as to the

8   total amount of product that is being

9   shipped, right?

10   MR. BARKER: Object to form.

11   THE WITNESS: So when we get

12   the new enhancements, the products

13   that we would use are Duragesic

14   and Concerta and Ultram that we

15   have now. That's the historical

16   orders.

17   And those products are

18   pretty consistent in the ordering

19   pattern. So by running them

20   through, we're not going to get

21   any more new hits, because for the

22   past orders for the past few

23   years, because we divested

24   Nucynta --

Highly Confidential - Subject to Further Confidentiality Review

```
 1    BY MR. JANUSH:

 2          Q.    Sure.

 3          A.    So it would be a very -- to

 4    have customer service -- instead of

 5    focusing on our current products and

 6    using this new threshold to get -- we

 7    are -- it would just -- it wouldn't be

 8    time well spent because we already know

 9    that those past orders, the customer's

10    ordered the same time, the same

11    quantities, we know the ordering history,

12    anything that's atypical that arrived

13    would have been flagged in our existing

14    program.  So that is why we didn't see

15    the value at that time.

16          Q.    Got it.  Okay.  I'm going to

17    show you an example live in a moment.

18          A.    Okay.

19          Q.    And we're going to go back

20    in time to see how Terrance's

21    recommendation would have impacted you

22    years ago before you divested Nucynta,

23    fair?

24          A.    Sure.
```

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   Before doing that I want to

2   go Paragraph 13.

3   MR. BARKER: Before you ask

4   that question, Evan, are you

5   representing that the highlighting

6   is in the original document.

7   MR. JANUSH: No, I am

8   absolutely not. I highlighted all

9   of this. I apologize. I can give

10   you clean copies here. But

11   everything here is something I

12   highlighted.

13   MR. BARKER: Including

14   the --

15   MR. JANUSH: Including the

16   yellow highlighting that's

17   computer highlighted by me to

18   focus your attention on it. I

19   didn't want to play hide the ball.

20   I wanted you to see exactly what I

21   was going to turn to when I

22   touched this page. I made that

23   highlight.

24

Highly Confidential - Subject to Further Confidentiality Review

1   BY MR. JANUSH:

2   Q.   So that highlight in

3   brighter gold at the bottom of Paragraph

4   13 states, "It appears that the JOM

5   suspicious order monitoring program" --

6   or "suspicious order monitoring has not

7   reported an order for controlled

8   substances as suspicious during its time

9   in operation."

10   Do you see that?

11   A.   Yes, I do.

12   Q.   Do you agree with that?

13   A.   We have not reported a

14   suspicious order, yes.

15   Q.   And when you say we have not

16   reported a suspicious order, you are

17   referring to the fact that we, JOM, or

18   Johnson & Johnson, has not reported a

19   suspicious order to the DEA; is that

20   correct?

21   A.   Right, we have -- might have

22   reported investigated orders to DEA. But

23   none were deemed suspicious.

24   Q.   Did you report investigated

1   orders to DEA?

2   A.   We -- I recall, and I think

3   we spoke previously in 2007, when there

4   was a Cardinal distribution license

5   issue, and we saw an increased demand in

6   California. And we reached out to San

7   Francisco DEA, explained our algorithm,

8   explained that we saw an increased demand

9   in this DC because three other DCs lost

10   their license. We didn't -- we

11   investigated it. It made sense, and we

12   didn't deem it suspicious.

13   Q.   And beyond that reporting,

14   did you ever report an order to the DEA?

15   A.   We had informal discussions

16   with DEA asking if they wanted every

17   order we investigated. But no, none that

18   was suspicious.

19   Q.   You didn't like this

20   language that I highlighted in gold in

21   your audit report, did you? And I'm

22   circling it in red. You didn't like it,

23   right?

24   MR. BARKER: Object to form.

Highly Confidential - Subject to Further Confidentiality Review

```
 1                    THE WITNESS:  I don't know

 2          what -- I -- it's -- we haven't

 3          done any suspicious -- we haven't

 4          reported suspicious --

 5   BY MR. JANUSH:

 6          Q.    You didn't like having the

 7   language in the -- in the report and you

 8   wanted it wiped out and deleted, didn't

 9   you?

10                    MR. BARKER:  Object to form.

11                    THE WITNESS:  I don't

12          recall.

13   BY MR. JANUSH:

14          Q.    I'll work to refresh your

15   recollection.

16                    (Document marked for

17          identification as Exhibit

18          Janssen-Dempsey-27.)

19   BY MR. JANUSH:

20          Q.    I'll mark Exhibit 27 a

21   document beginning with Bates

22   JAN-MS-05444648.

23                    I'm going to have you turn

24   to the last page of the e-mail.
```

Highly Confidential - Subject to Further Confidentiality Review

```
1              And this is a family

2    document, and it's attaching a new draft

3    of the same date, Drug and Chemical

4    Advisory Group, evaluation of the

5    suspicious order monitoring system audit

6    that is JAN-MS-05444650.

7              But for the moment, I'm

8    going to look at 649, the second page of

9    the e-mail.

10             I'm going to draw your

11   attention to your e-mail to Terry.

12             And you wrote, "Hello,

13   Terry.  During the review last week,

14   Brian pointed out one statement that I

15   think needs to be clarified.  The below

16   statement in red can be misleading.

17   Perhaps you could consider rewording?

18   Something like, 'Due to the current

19   algorithm and order investigation

20   process, there has not been any deemed

21   suspicious that would require

22   reporting.'"

23             Do you see that?

24        A.    Yes, I do.
```

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   And the sentence that you're

2   referring to is the last sentence that is

3   also being boxed by me.   "It appears that

4   the JOM suspicious order monitoring has

5   not reported an order for controlled

6   substances as suspicious during its time

7   in operation."

8   Isn't that right?

9   A.   Yes.

10   Q.   Okay. So Terry -- Terrance

11   Woodworth wrote back to you, "Hi, Michele

12   and Brian. I hope you are both doing

13   well. I am happy to just delete this

14   sentence altogether."

15   Do you see that?

16   A.   Mm-hmm.

17   Q.   And he says, "It really

18   doesn't fit well with the recommendation

19   being made. What do you think? And if

20   this is okay, do you want me to send you

21   a new draft with the sentence omitted?

22   Thank you, Michele and Brian!!"

23   Do you see that?

24   A.   Yes.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   Does this refresh your

2   recollection of what happened?

3   A.   Yes, it does.

4   Q.   And then on the first page,

5   Brian Strehlke writes back, "Hi, Terry.

6   That sounds fine to me. From our time

7   spent together in December, I took away

8   that: One, our system has been working

9   well; two, there is an identified

10   weakness with Schedule III orders that

11   come in late in the day requiring manual

12   processing to verify their non-suspicious

13   nature; three, you made recommendations

14   necessary to enhance our process to meet

15   changing regulatory expectations; four,

16   there have been no orders identified as

17   suspicious and there have been none

18   reported.

19   "Are you in agreement with

20   the above?"

21   Did I read that right?

22   A.   Yes.

23   Q.   Okay. Now, let's -- going

24   with Number 2, "There is an identified

Highly Confidential - Subject to Further Confidentiality Review

1   weakness with Schedule III orders that

2   come in late in the day requiring manual

3   processing to verify their non-suspicious

4   nature."

5   We have already established

6   that that same issue can exist with

7   Schedule II orders that come in late in

8   the day as well, right?

9   MR. BARKER: Object to form.

10   BY MR. JANUSH:

11   Q.   Meaning a Schedule II order

12   that comes in late in the day, regardless

13   of whether it comes in on EDI or though a

14   manual 222 documentation, still can be

15   captured -- still may not be captured by

16   the running of the suspicious order

17   monitoring algorithm late in the day,

18   right?

19   MR. BARKER: Object to form.

20   THE WITNESS: If the human

21   error -- customer service puts the

22   order on after the time.

23   BY MR. JANUSH:

24   Q.   Okay. And Terrance responds

1   to Brian, doesn't he, at the top of this

2   e-mail string?

3   A.   Yes, he does.

4   Q.   And he says, "Hi, Brian.

5   Okay. Sentence has been deleted!"

6   Do you see that?

7   A.   Mm-hmm.

8   Q.   "Yes, I am in agreement with

9   all of your takeaway comments, and I

10   would add that we felt the current

11   algorithm was one-dimensional and thus

12   had some draw backs that could be

13   addressed by enhancing the algorithm."

14   Do you see that?

15   A.   Yes, I do.

16   Q.   Okay. Did you agree with

17   his conclusion?

18   A.   That -- it just factored --

19   yes, that it was only on quantity.

20   Q.   Okay. And going -- going to

21   the bottom again to Brian's e-mail. At

22   Number 3, Brian sought to confirm, "You

23   made recommendations necessary to enhance

24   our process to meet changing regulatory

Highly Confidential - Subject to Further Confidentiality Review

1   expectations."

2   Do you see that?

3   A.   Yes, I do.

4   Q.   But, there were no changing

5   regulatory expectations as it concerned

6   the three factors of an algorithm that

7   we've been addressing in Joseph

8   Rannazzisi's letter of December 2007,

9   right?

10   MR. BARKER: Object to form.

11   THE WITNESS: The three

12   factors, the C.F.R., had not

13   changed; however, there were

14   changes through interaction with

15   DEA and going to conferences where

16   there were additional

17   expectations.

18   BY MR. JANUSH:

19   Q.   But the three factors hadn't

20   changed, right?

21   A.   No, the factors had not

22   changed.

23   Q.   Okay. And if you turn to

24   page ending in 663 in the audit that's

Highly Confidential - Subject to Further Confidentiality Review

1   attached, and you go to Paragraph 13, the

2   statement that you and Brian Strehlke

3   asked to be removed would have appeared

4   here.

5   A.   I would like to correct, we

6   didn't ask it to be removed. Terry said

7   that he would be happy to delete it. And

8   even Brian said there were no orders

9   identified as suspicious and thus had

10   none reported. It was Terry that said

11   sentence has been deleted.

12   Q.   Except he said, "What do you

13   think?" Which means -- if you go back to

14   the e-mail, he put the ball in your

15   court. "What do you think?"

16   Do you see that?

17   MR. BARKER: Object to form.

18   BY MR. JANUSH:

19   Q.   I'm highlighting it. I'm

20   boxing it in.

21   A.   Yes. But --

22   Q.   And the answer was, "That

23   sounds fine to me."

24   Do you see that?

Highly Confidential - Subject to Further Confidentiality Review

 1   A.   That is what Brian said,

 2   yes.

 3   Q.   So Brian had the opportunity

 4   to say, "No, don't delete it. We

 5   disagree," correct?

 6   A.   Yes.

 7   Q.   And he didn't do it, right?

 8   A.   Yes.

 9   Q.   And, again, going back to

10   the deletion, it would have appeared

11   where I'm drawing this red underline at

12   the end of Paragraph 13, correct?

13   A.   Yes.

14   Q.   That's not all that was

15   deleted, is it?

16   MR. BARKER: Object to form.

17   THE WITNESS: No.

18   BY MR. JANUSH:

19   Q.   Do you remember other stuff

20   that was deleted, other language?

21   A.   As we were working through

22   the report in identifying how to actually

23   perform the enhancements, we did identify

24   some that we didn't -- we had some

Highly Confidential - Subject to Further Confidentiality Review

1   issues -- not issues, but we didn't

2   understand why it was there.

3   Q.   Okay.

4   (Document marked for

5   identification as Exhibit

6   Janssen-Dempsey-28.)

7   BY MR. JANUSH:

8   Q.   I'm going to hand you what's

9   been marked as Exhibit 28.

10   MR. JANUSH: Counsel.

11   MR. BARKER: Thank you.

12   BY MR. JANUSH:

13   Q.   And this is Bates-numbered

14   JAN-MS-05444781.

15   And I'm going down to your

16   e-mail, middle of the -- I'm going to

17   draw a line to make it easier for you, if

18   you want to look at the screen too. Your

19   e-mail, second half of the first page.

20   You're writing to Terry. "Some other

21   tweaks I thought I would mention for your

22   consideration."

23   Do you see that?

24   A.   Yes.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   And then go down to the

2   bottom. Last sentence. "Also, in

3   thinking this one over: Take past order

4   examples and evaluate their

5   circumstances, order patterns, and" --

6   flip the page -- "activity against

7   revised algorithms to determine

8   discrepancies or adjustment needed."

9   Quote, or I should say end

10   quote.

11   And your statement that I've

12   highlighted is: "I don't think we want

13   to question release decisions after the

14   fact. We should remove this item. The

15   intent will be covered when we implement

16   867 chargeback/data analytics and

17   reviewing actions taken against DEA

18   registrants."

19   Do you see that?

20   A.   Yes, I do.

21   Q.   Now, I'm going to introduce

22   you -- introduce to you, Exhibit 29,

23   which is another copy of the same draft

24   audit from Terrance Woodworth and the

Highly Confidential - Subject to Further Confidentiality Review

1   Drug and Chemical Advisory Group. The

2   Bates numbering is JAN-MS-05444783.

3   (Document marked for

4   identification as Exhibit

5   Janssen-Dempsey-29.)

6   BY MR. JANUSH:

7   Q.   And I am going to draw your

8   attention to Paragraph 12. And right

9   where I'm drawing the line on the screen

10   for your benefit is where the last bullet

11   was deleted; isn't that right?

12   A.   Yes.

13   Q.   Did you hire Terrance

14   Woodworth to be your independent

15   suspicious order monitoring auditor or to

16   be your lackey?

17   MR. BARKER: Object to form.

18   THE WITNESS: We hired him

19   to do an audit of our program.

20   BY MR. JANUSH:

21   Q.   Did you hire him to be an

22   independent auditor or to be your lackey?

23   MR. BARKER: Object to form.

24   THE WITNESS: We hired him

Highly Confidential - Subject to Further Confidentiality Review

1   to be an auditor of our program

2   and provide us enhancements of

3   what he is currently seeing out in

4   industry.

5   BY MR. JANUSH:

6   Q.   Did you expect him to work

7   independently and give his independent

8   feedback to you?

9   A.   We expected him to give his

10   feedback. And that's what this audit was

11   for.

12   Q.   Why did you play a role in

13   editing his audit?

14   A.   Because as this was being

15   developed, there were changes happening.

16   As -- you didn't mention,

17   but the whole funding item that he

18   suggested, which might have been fine in

19   the past, but given what Senator

20   McCaskill's -- the whole group was

21   identifying, that all these

22   pharmaceutical companies providing

23   funding, we didn't think that was

24   appropriate in this document.

1   So we took his -- his

2   recommendations; however, we also looked

3   at the current environment to see.

4   MR. JANUSH: Move to strike

5   all aspects of that answer

6   concerning funding.

7   BY MR. JANUSH:

8   Q.   I didn't ask about funding,

9   did I?

10   A.   No, but it was an item that

11   we also asked to be changed. Just try to

12   explain, you know, that he gave his

13   recommendations; however, there were

14   different nuances happening out in the

15   environment that would require different

16   wording.

17   Q.   You all weren't handcuffed

18   to abide by every recommendation in his

19   audit, right? You could have disagreed

20   with his audit concerning anything

21   related to funding and left it in, true?

22   A.   This was -- this was his

23   recommendations that we consider --

24   Q.   No, that's not what I'm

1   asking. You could have kept the language

2   as it was and ignored certain quoted

3   language, true or false?

4   A.   True.

5   Q.   And instead you actively

6   affirmatively chose to involve yourself

7   in an independent auditor's draft and

8   edit his draft, true or false?

9   MR. BARKER: Object to form.

10   THE WITNESS: True, we made

11   changes.

12   MR. JANUSH: Okay. We are

13   going to toggle now to the

14   computer HDMI hookup. And we are

15   going to mark this exhibit as

16   Exhibit 35 (sic).

17   (Document marked for

18   identification as Exhibit

19   Janssen-Dempsey-30.)

20   BY MR. JANUSH:

21   Q.   It is an Excel file too

22   large to produce at this deposition, so

23   we'll pull it up on this 49-inch screen.

24   It's JAN-MS-03739863.

Highly Confidential - Subject to Further Confidentiality Review

1   And I have filtered this

2   Excel file to just address a portion of

3   it related to your customer, Cardinal

4   Health, and to go back in time to look at

5   Nucynta sales. And at the bottom, you'll

6   see the tab, "SAP direct sales."

7   Do you see that?

8   A.   Yes.

9   Q.   And I'm going to draw your

10   attention to -- close to the top of the

11   screen, about four or five lines down,

12   I've highlighted it or grayed it in. It

13   is Line 6016. Or maybe that's not Line

14   6016. But it ends in column O,

15   $322,608.96.

16   And Column N addresses

17   Nucynta tablets, 100 milligrams, 100s, 24

18   count, and 864 as the quantity number.

19   Do you see that?

20   MR. BARKER: I'm going to

21   object to form and to the line of

22   questioning because I cannot see

23   what -- I'm looking up at that

24   screen, and I can't see what

Highly Confidential - Subject to Further Confidentiality Review

```
 1            you're.

 2                 MR. JANUSH:  Okay.  You have

 3            a right to walk up to the screen.

 4                 MR. BARKER:  And I'm happy

 5            to do that.  I'm going to pass

 6            behind the witness.

 7                 MR. JANUSH:  If you'd like.

 8            If you'd like.  Since I have the

 9            screen in front on have me, let me

10            give you this and make life easier

11            for you.  Okay.

12                 MR. BARKER:  That's helpful.

13                 MR. JANUSH:  There you have

14            a monitor.  Let the record reflect

15            that I've handed my monitor to

16            Mr. Barker, opposing counsel.  And

17            it is approximately 24 inches from

18            him.  And it appears to be a

19            20-inch wide-screen monitor.

20                 MR. BARKER:  Okay.  I'm also

21            objecting because I don't -- I

22            don't know how this document has

23            been filtered, and I also don't

24            know what --
```

Highly Confidential - Subject to Further Confidentiality Review

1   A.   No, I don't. Like I said

2   this is the project team that's managing

3   this. I'm a high level watching it.

4   Q.   And who manages the

5   product --

6   A.   Valerie.

7   Q.   -- project team?

8   Valerie Chikwendu?

9   A.   Mm-hmm.

10   Q.   And --

11   A.   I do know there's been a few

12   since then. This was the initial

13   kickoff, and more followed as we got to

14   the threshold.

15   Q.   So when did you start

16   working with The Analysis Group? Was it

17   in May after receiving this, in May of

18   2018, after receiving this proposal?

19   A.   I believe we had them -- we

20   had a workshop where they came in, and I

21   can't remember what day it was.

22   Q.   Do you have notes from that

23   workshop?

24   A.   It wasn't my -- I just

1   attended it. I didn't lead the workshop.

2   But I think it was July.

3   But yeah, so this is when we

4   were initially engaging them and getting

5   the funding to pay for them to come to

6   the workshop.

7   Q.   Incidentally, does Terrance

8   Woodworth and his company also assist in

9   creating revised algorithms?

10   A.   I don't know.

11   Q.   Did you ever investigate

12   that with Terrance Woodworth?

13   A.   No.

14   Q.   No. Why not?

15   A.   I just -- we --

16   Q.   In other words, what made

17   you walk away from working with Terrance

18   Woodworth and move towards working with

19   The Analysis Group?

20   MR. BARKER: Object to form.

21   THE WITNESS: Oh, at a -- at

22   an HDA conference, The Analysis

23   Group was there. And they

24   introduced themselves. And I saw

Highly Confidential - Subject to Further Confidentiality Review

1   what they provide, the services.

2   And we thought they were more

3   relevant to the actual -- doing

4   the statistical analysis.

5   BY MR. JANUSH:

6   Q.   Thought what was more

7   relevant?

8   A.   What they do, the services

9   that they provide, is more in line with

10   what we needed for the thresholds. I was

11   not aware that Terry could provide those

12   services. So we didn't even think to ask

13   Terry.

14   Q.   When you say the services

15   that they provide, can you elaborate on

16   that?

17   A.   The Analysis Group aids

18   companies with looking at their data to

19   set up thresholds for suspicious order

20   monitoring.

21   Q.   Okay. But lots of companies

22   do that. How did they do it differently

23   than other companies? You were

24   explaining that there was something

1   different about The Analysis Group.

2   A.   Well, you were asking me to

3   compare to Terry.

4   Q.   Right.

5   A.   And I wasn't -- I had not

6   heard of anything that Terry -- the

7   services that Terry provides.

8   Q.   You said, "And we thought

9   they were more relevant to the actual --

10   doing the statistical analysis." And I

11   said, "What was more relevant?"

12   I'm trying to dig a little

13   deeper and find out what was it that was

14   more relevant that The Analysis Group

15   could provide you with.

16   MR. BARKER: Object to form.

17   THE WITNESS: Well, your

18   question is, why didn't we use

19   Terry.

20   BY MR. JANUSH:

21   Q.   That's not my question now.

22   A.   I'm sorry. Okay. Well,

23   when we engaged with The Analysis Group,

24   what services they communicated to us

Highly Confidential - Subject to Further Confidentiality Review

1   appeared to support the enhancements that

2   we wanted to make with our program

3   because --

4   Q.   And what services were

5   those?

6   A.   -- they --

7   MR. BARKER: Let's slow this

8   down. Let her finish her answer

9   before we start with the next

10   question, please. Thank you.

11   THE WITNESS: So when we

12   engaged with them, they told us

13   that they come into companies that

14   distribute controlled substances.

15   They can assist them in

16   configuring their own systems with

17   threshold algorithms, or they

18   could provide -- or they can

19   provide guidance on other systems

20   that could do these calculations.

21   So they do the statistics based on

22   historical data and help the

23   companies configure their IT

24   systems to do the own threshold

1   analysis.

2   And that's what we basically

3   needed. We needed somebody to

4   help us take our historical data

5   and determine what statistics does

6   DEA expect to see on that data and

7   set up thresholds for our

8   products.

9   BY MR. JANUSH:

10   Q.   What are the statistics that

11   you believe DEA expects to see to set up

12   thresholds on your products?

13   A.   They expect us to be

14   monitoring quantity, frequency, and

15   patterns. And The Analysis Group has had

16   experience with other companies

17   identifying what kind of thresholds are

18   needed to address those factors.

19   Q.   And again, the expectation

20   from the DEA concerning the requirement

21   that a registrant monitor quantity,

22   frequency, and patterns is not new,

23   right?

24   A.   No. But we were currently

Highly Confidential - Subject to Further Confidentiality Review

1   doing it from an algorithm and then the

2   manual for the pattern and frequency.

3   And we wanted one system that would do it

4   all automatically.

5   Q.   You're not testifying today

6   that you were in realtime every day when

7   an order was being placed doing an

8   investigation of every order for pattern

9   and frequency unless an order was first

10   flagged by your algorithm, right?

11   MR. BARKER: Object to form.

12   THE WITNESS: There are --

13   obviously the orders that are

14   flagged do get the investigation.

15   But we know the typical

16   ordering pattern of the customers,

17   if they order either once a week

18   or -- the big three, or twice a

19   week. So the customer service

20   knows the typical ordering

21   patterns, that if they saw

22   somebody order twice, that they

23   would question it.

24   So that's what I'm saying,

Highly Confidential - Subject to Further Confidentiality Review

```
 1              the human element was trying to

 2              follow the frequency and pattern.

 3              And we just wanted to make the

 4              algorithm do all of it at once,

 5              versus relying on a manual.

 6   BY MR. JANUSH:

 7         Q.    Except for Cardinal, where I

 8   showed you on that spreadsheet, was

 9   ordering three days apart from the prior

10   order for the same drug, that's not

11   something that would be flagged by your

12   algorithm, correct?  And it's something

13   that you knew happened because you knew

14   Cardinal's ordering schedule, right?

15                  MS. BOODY:  Object to form.

16                  THE WITNESS:  We knew that

17              they ordered Mondays and

18              Wednesdays for example.  The

19              quantity, we knew that that

20              location was the main hub that

21              Cardinal supplied all of their DCs

22              and pharmacies.  So -- and that

23              quantity was obviously less than

24              the threshold unless it was
```

1   flagged as atypical. So...

2   BY MR. JANUSH:

3   Q.   I'm going to move on to what

4   I've marked as Exhibit 33.

5   (Document marked for

6   identification as Exhibit

7   Janssen-Dempsey-33.)

8   BY MR. JANUSH:

9   Q.   This looks like the

10   preliminary algorithm for --

11   MR. JANUSH: I have two

12   copies to share.

13   MR. BARKER: How many pages

14   should this be?

15   MR. JANUSH: It begins on

16   JAN-MS-05444640. And that is Page

17   1.

18   And it ends on Page 7,

19   JAN-MS-05444646.

20   MR. BARKER: One of the

21   copies you handed me goes that

22   far. The other one only has six

23   pages, going through 45. But I do

24   appear to have --

Highly Confidential - Subject to Further Confidentiality Review

1   MR. JANUSH: Here you go.

2   There's a corrected one.

3   MR. BARKER: Thanks. You

4   want that back. There you go.

5   MR. JANUSH: And that

6   explains my problem. If you can

7   give that to Cardinal's counsel.

8   MR. BARKER: Well, that

9   should be a complete copy.

10   MS. WINCKEL: I can look on

11   here.

12 BY MR. JANUSH:

13   Q.   And this is dated

14 preliminary draft February 1st, 2019.

15   Do you see that?

16   A.   Yes.

17   Q.   Have you seen this before?

18 This is titled "Preliminary Algorithm

19 Logic For Suspicious Order Monitoring"?

20   A.   I have not seen this before.

21   Q.   Okay. So I'm going to

22 represent that this was not produced with

23 any family, it was just produced

24 generally. But since you have not seen

1   it before, I'll just ask you to take a

2   look at it and ask if you can explain it.

3   And if the answer -- your answer will

4   dictate what we do next.

5   MR. BARKER: Object to form.

6   You're asking her to explain

7   a document that she's never seen

8   before.

9   THE WITNESS: Yes, this is

10   trying to explain how SAP is going

11   to work in --

12   BY MR. JANUSH:

13   Q.   Are you involved in the new

14   algorithm logic for suspicious order

15   monitoring?

16   A.   I am not involved in the

17   tactical execution, no.

18   Q.   Okay. Who are the folks

19   that are involved in the tactical

20   execution going forward?

21   A.   Stephanie Dixon. She -- the

22   control substance compliance manager.

23   IT.

24   Q.   Who from IT?

1   marketing group for our new product.

2   Q.   What new product?

3   A.   Esketamine.

4   Q.   Okay. And here you were

5   addressing in the middle of the page, on

6   February 14, 2018, a recap of what took

7   place during the December workshop with

8   Terrance Woodworth, your outside auditor

9   for suspicious order monitoring; is that

10   right?

11   A.   Yes.

12   Q.   And it states at the bottom,

13   "The commercial excellence team

14   introduced Brian and I to Sue.

15   IntegriChain is beginning to see a future

16   need in providing companies with trend

17   analysis beyond the wholesaler to

18   pharmaceutical companies and provided the

19   following scope of work. Suspicious

20   order monitoring data analytics is new to

21   us and other companies as well. I

22   recently saw my counterparts at

23   Mallinckrodt in D.C. and I asked them

24   what they are doing and was told they are

1   paying Quintiles/IMS, now IQVia, to do

2   the analysis for them."

3   Did I read that right?

4   A.   Yes, you did.

5   Q.   And then you asked if the

6   attachments could be reviewed and be

7   ready -- if they could be ready to

8   provide feedback at a teleconference that

9   you'll set up next week; is that correct?

10   A.   Yes.

11   Q.   And the attachments, Number

12   2, one is the IntegriChain substance

13   order analytics and reporting overview,

14   dated February 14, 2018. And the other

15   is an IntegriChain statement of work

16   presented to Janssen Pharmaceuticals,

17   Inc., for controlled substance order

18   compliance, also dated February 14, 2018;

19   is that right?

20   MR. BARKER: Objection.

21   THE WITNESS: Yes.

22   MR. BARKER: You misread the

23   statement of that document.

24   THE WITNESS: Statement of

Highly Confidential - Subject to Further Confidentiality Review

1   work presented at Janssen

2   Pharmaceuticals for controlled

3   substance order analytics.

4   BY MR. JANUSH:

5   Q.   Sorry. Actually, statement

6   of work presented to Janssen

7   Pharmaceuticals, Inc., for controlled

8   substance order analytics, right?

9   A.   Yes.

10   MR. BARKER: Object to form.

11   BY MR. JANUSH:

12   Q.   And the statement of work is

13   Bates Number JAN-MS-03060712.

14   And the IntegriChain slide

15   deck is JAN-MS-03060704.

16   Had you met with

17   IntegriChain before February 14, 2018,

18   prior to being provided with this

19   statement of work?

20   A.   I can't recall the first

21   time that I met them.

22   Q.   Okay. What's your

23   understanding of what IntegriChain is --

24   let's take a step back.

Highly Confidential - Subject to Further Confidentiality Review

1   Janssen wound up retaining

2   IntegriChain, correct?

3   A.   JOM retained them last -- we

4   got the -- this SOW approved last

5   December. Janssen has been using

6   IntegriChain. The trade marketing folks

7   have been using them.

8   Q.   Right. Janssen, for

9   purposes of sales and marketing, has been

10   using IntegriChain data dating back to at

11   least 2011; is that right?

12   A.   I don't know the actual

13   date. But I do know that they've been

14   using this data.

15   Q.   And we -- we addressed that

16   at the last deposition with a document

17   showing ValueTrak and IntegriChain data

18   in 2011 and 2012; is that right?

19   A.   You did show me that trade

20   analytics slide deck.

21   Q.   And when was the first time

22   that compliance started working with

23   IntegriChain?

24   A.   It was when commercial

Highly Confidential - Subject to Further Confidentiality Review

1   excellence introduced Brian Strehlke and

2   I to IntegriChain. And I don't remember

3   when. I guess it was in February.

4   Q.   Of 2018?

5   A.   Yeah.

6   Q.   What is your understanding

7   of what IntegriChain brings to the table

8   in terms of assisting with Janssen's

9   to-be-updated or revised suspicious order

10   monitoring program?

11   MR. BARKER: Object to form.

12   THE WITNESS: What

13   IntegriChain can assist us with is

14   identifying at the pharmacy level,

15   if there's any trends with our

16   products.

17   Right now, our 867 data is

18   blinded, and IntegriChain can get

19   the unblinded data and do the

20   analysis off our data to let us

21   know at the pharmacy level, how

22   does our product compare to, I

23   guess, national averages is what

24   they explained to us. And they

1   could do regional analysis and let

2   us know if there is any trends

3   with our product that we need to

4   investigate.

5   BY MR. JANUSH:

6   Q.   For example, on Page 2 of

7   the slide deck, "Identify pharmacies with

8   high volume purchasing trends leveraging

9   product and market deciles." Is that

10   right?

11   A.   That is what -- yes.

12   Q.   Okay. And that they can

13   also assist, based on, going to the last

14   bullet, "Based on historical purchasing

15   trends, set volume thresholds at the

16   pharmacy and distributor level. Total

17   volume can be rolled up to distributor as

18   an input into the order monitoring

19   system."

20   Do you see that?

21   A.   Yes.

22   Q.   Are you doing that now going

23   forward? Are you implementing this?

24   A.   This is the Track 2 of our

 1   project where we will be looking

 2   downstream to determine whether, based on

 3   what the wholesalers ship out, if we need

 4   to adjust the thresholds. So, yes, our

 5   new enhancements will be doing this.

 6   Q.   And to be clear, this is the

 7   kind of third-party data vendor that

 8   assists in unblinding sales that you make

 9   to your distributor, such that they are

10   able to report back to you when a

11   Cardinal, as an example, may sell to a

12   CVS, they may be able to report back to

13   you which CVS store your products are

14   ending up at; is that right?

15   MR. BARKER: Object to form.

16   THE WITNESS: IntegriChain

17   can give us visibility to the CVS

18   level.

19   BY MR. JANUSH:

20   Q.   Okay. This is the know your

21   customers' customer data, so to speak,

22   right?

23   MR. BARKER: Object to form.

24   BY MR. JANUSH:

1   Q.   Remember we talked about

2   that concept of know your customers'

3   customer, in the context of the

4   Mallinckrodt DEA investigation?

5   MR. BARKER: Object to form.

6   THE WITNESS: We were told

7   to -- yes. Well, you need to know

8   where your products are going

9   downstream.

10   BY MR. JANUSH:

11   Q.   Right. And that refers to

12   knowing your customers' customer, right?

13   A.   Yes.

14   Q.   And knowing your customers'

15   customer was not a new concept for you,

16   was it? You learned about this concept

17   when you benchmarked with Jack Crowley at

18   Purdue on March 21, 2012, didn't you?

19   MR. BARKER: Object to form.

20   THE WITNESS: We understood

21   that Purdue was doing that.

22   BY MR. JANUSH:

23   Q.   And by doing that, what do

24   you mean?

 1   A.   That they were doing the

 2   downstream pharmacy analysis because of

 3   the oxycodone situation.

 4   Q.   So Purdue was knowing their

 5   customers' customer; is that right --

 6   what you're testifying to?

 7   MR. BARKER: Object to form.

 8   THE WITNESS: That is what

 9   they communicated to us.

10   (Document marked for

11   identification as Exhibit

12   Janssen-Dempsey-36.)

13   BY MR. JANUSH:

14   Q.   I'm going to hand you what's

15   been marked as 36. It actually is a

16   document that references the know your

17   customers' customer. Its Bates number is

18   JAN-MS-02984629, and this is when in July

19   of 2013, Jack Crowley, formerly of

20   Purdue, then on his own as Crowley

21   Associates, was pitching to Janssen an

22   abuse and diversion detection program,

23   isn't it?

24   MS. POWER: Object to form.

```
 1              THE COURT REPORTER:  Can you

 2        identify who you are?

 3              MS. POWER:  This is Caroline

 4        Power for the Purdue defendants.

 5              MR. JANUSH:  Representing

 6        which defendant?

 7              MS. POWER:  The Purdue

 8        defendants.

 9              MR. JANUSH:  Thank you.

10   BY MR. JANUSH:

11        Q.   Let's go to the first line

12   of the middle of the e-mail.  "Hello,

13   Ron.  Here are a preliminary rough notes

14   on the subject of our recent

15   conversation.  DEA impact on pharmacy

16   stocking C-II medications - developing a

17   system for your abuse and diversion

18   detection program - prescribers of

19   concern."

20              Did I read that right?

21              MR. BARKER:  Object to form.

22              THE WITNESS:  Yes.

23   BY MR. JANUSH:

24        Q.   And it says, "We discussed
```

1   training for the sales force how to

2   recognize what is suspicious or a cause

3   for concern, that this is a delicate

4   balance and generally what steps need to

5   be taken to bring information into the

6   home office, so to speak, how to handle

7   that information, and how to move

8   forward."

9   Did I read that correctly?

10   MR. BARKER: Object to form.

11   THE WITNESS: Yes.

12   BY MR. JANUSH:

13   Q.   And at the bottom, it's

14   addressing five different suggestions,

15   after which Jack writes, "'Know your

16   customers' customers,' Janssen's

17   suspicious or noteworthy order monitoring

18   system and collaboration/mutual support

19   with authorized distributors."

20   Did I read that correctly?

21   A.   Yes.

22   Q.   From July 26, 2013, when

23   Jack Crowley pitched this abuse and

24   diversion detection program that follows

1   at JAN-MS-02984631 with his presentation

2   to the present date, you didn't implement

3   a know your customers' customer program

4   to address prescribers of concern at the

5   sales force level, did you?

6   A.   It wasn't an expectation.

7   We weren't told by DEA to do this. But I

8   am not aware if Ron implemented that. I

9   did not. I can't speak on behalf of Ron

10 what he did with this. But I do know

11 that I did not.

12   Q.   And just to wrap up this

13 document, the attachment from Jack

14 Crowley, Bates Number JAN-MS-02984631,

15 concerned his pitch on how to address

16 prescribers of concern with a stated

17 goal, in the middle of the first page --

18 I'm going to direct your attention to the

19 first page of his title page. "Goal -

20 make sure that the company is marketing

21 to the proper prescribers."

22   Do you see that?

23   A.   Yes, I do.

24   Q.   "Secondary goal, to provide

1   guidance and require the sales

2   representatives to recognize, detect, and

3   report suspicious" -- "suspected abuse

4   and suspected diversion by healthcare

5   practitioners of Janssen products."

6   Do you see that?

7   MR. BARKER: Object to form.

8   THE WITNESS: Yes, I do.

9   BY MR. JANUSH:

10   Q.   Do you remember internally

11   pitching this within Janssen as something

12   that you had an interest in having Jack

13   present on?

14   MR. BARKER: Object to form.

15   THE WITNESS: I recall that

16   Ron asked me if I knew anybody

17   that could talk to him about

18   training of the sales force. And

19   I introduced him to Jack Crowley.

20   BY MR. JANUSH:

21   Q.   You were friends with Jack

22   though, right?

23   A.   I have known Jack for many

24   years, yes.

1   Q.   So if Jack got retained

2   after you introduced him, you would have

3   known that, wouldn't you?

4   A.   Yes, I would have.

5   Q.   And to this day, you

6   don't -- you have no knowledge that he

7   was retained, right?

8   A.   He was not retained.

9   (Document marked for

10   identification as Exhibit

11   Janssen-Dempsey-37.)

12   BY MR. JANUSH:

13   Q.   I'm going to move on to

14   Exhibit 37, JAN-MS-03124101.

15   MR. JANUSH: Whoops. I

16   marked the wrong one.

17   MR. BARKER: Feel free to

18   mark the one with all your notes

19   on it if you want. That's all

20   right.

21   BY MR. JANUSH:

22   Q.   I'm going to just address

23   this. This is the July 24, 2013, Version

24   2, work instruction, document entitled

1   "JOM Customer Service Suspicious Or

2   Excessive Orders." Document Number DS/WI

3   3824, Version 2.0.

4   Do you see that?

5   A.   Yes.

6   Q.   This is the Version 2 of the

7   suspicious order monitoring program work

8   instruction that you played a role in

9   putting together after you came on board

10   as director of controlled substance

11   compliance in 2012; is that right?

12   MR. BARKER: Object to form.

13   THE WITNESS: Yes.

14   BY MR. JANUSH:

15   Q.   And just for the record,

16   this -- the purpose of this is stated at

17   1.1, "To define a process that complies

18   with DEA or state requirements to provide

19   information on any prescription order,

20   controlled or noncontrolled substances,

21   that could be considered potentially

22   suspicious or excessive," right?

23   A.   Yes.

24   Q.   And the algorithm that

Highly Confidential - Subject to Further Confidentiality Review

```
1    existed in Version 1.0 that we addressed

2    at the last deposition is the same here

3    isn't it, at 3.2.  It's 300 percent of

4    the calculated 12-month per weekly order

5    average; is that right?

6                   MR. BARKER:  Object to form.

7                   THE WITNESS:  Yes.  12-month

8         per weekly order average.

9                   (Document marked for

10              identification as Exhibit

11              Janssen-Dempsey-38.)

12   BY MR. JANUSH:

13        Q.    I'm going to mark for you

14   Exhibit 38.

15                And this is a different

16   document.  It's JOM customer support

17   services Schedule II through V order

18   processing and investigating suspicious

19   or excessive orders.  This is DS SOP

20   1235, Version 7.0, found at

21   JAN-MS-03115424.  And the effective date

22   of this is December 19, 2016.

23                And here too, the purpose of

24   this document is to provide instructions
```

1   for processing Schedule II through V

2   controlled substance orders and for

3   investigating suspicious or excessive

4   orders for controlled substances; is that

5   right?

6   A.   Yes.

7   Q.   And again, the algorithm is

8   stated differently. But it's stated in

9   the definition section at 3.1.

10   "Suspicious orders or excessive

11   controlled substances orders: Any

12   customers for Schedule II through V

13   orders exceeding three times the normal

14   12-month rolling demand."

15   Did I read that right?

16   A.   Yes.

17   Q.   And that's not 12 times the

18   normal 12-month weekly rolling demand

19   stated here. It's just 12 times the

20   normal 12-month -- three times the normal

21   12-month rolling demand; is that right?

22   MR. BARKER: Object to form.

23   THE WITNESS: That is what

24   it reads.

1   BY MR. JANUSH:

2   Q.   Did you have a role in

3   drafting this document?

4   A.   I reviewed it. But

5   customer -- this is a customer service

6   SOP. They wrote it.

7   Q.   Did you have the ability to

8   edit the document if you thought it was

9   in error?

10   A.   Yes.

11   Q.   Did you ever edit that

12   document?

13   A.   I don't recall.

14   (Document marked for

15   identification as Exhibit

16   Janssen-Dempsey-39.)

17   BY MR. JANUSH:

18   Q.   I'm marking 39. And I'm

19   handing copies to counsel.

20   JAN-MS-03115570. This appears to be an

21   e-mail from you to Belinda Corum dated

22   November 15, 2017, concerning

23   suspicious -- titled -- the subject is

24   2017 -- November 15, 2017, "Suspicious

Highly Confidential - Subject to Further Confidentiality Review

1   order monitoring minutes."

2   And it attaches DS/WI 3824,

3   the atypical order justification release

4   form work instruction, which can be found

5   at JAN-MS-03115575.

6   Do you see that work

7   instruction?

8   A.   Getting to it. Yes.

9   Q.   And have you seen this

10   document before?

11   A.   I have seen this document

12   before.

13   Q.   Did you ever edit this

14   document?

15   A.   Yes.

16   Q.   You did. Okay.

17   And here we have definition,

18   DEA unusual order quantity report at 3.1.

19   "A report that captures potentially

20   unusual quantities of controlled

21   substance orders, Schedule II through V,

22   that is equal to or greater than three

23   times (300 percent) the calculated

24   12-month order average."

1   potential enhancements that can be made

2   to that system as recommended by

3   Mr. Woodworth and DCAG, correct?

4   A.   This is when we were

5   initially discussing the opportunity.

6   This is before the report.

7   Q.   One of the workshop

8   attendees was Mr. Woodworth, correct?

9   A.   Yes. Yes, yes.

10   Q.   Okay. So on that topic, can

11   you read what your comment was?

12   A.   "Anytime we need to have a

13   review done each morning by personnel

14   leads to potential of error, the

15   correct" -- "the current remediation is

16   not the perfect" -- "not the preferred

17   long-term" -- "long-time solution."

18   Q.   Okay. What is it about the

19   current process that could lead to error?

20   A.   It is manually intensive,

21   requiring a person to do activity.

22   Q.   Would it be better if you

23   could get a computer to do that activity?

24   A.   Yes.

1   Q.   Just like in 2005, you

2   upgraded to a computer system that did

3   the stuff that you were doing manually

4   before, correct?

5   A.   Correct.

6   Q.   Okay. Does someone have to

7   manually hold back the order until the

8   suspicious order monitoring protocol is

9   executed?

10   A.   Any controlled substance

11   order that is put into SAP goes in this

12   business manager hold, and someone

13   physically have has to go into SAP and

14   release it after all the processing is

15   done.

16   Q.   So all the orders are

17   automatically held, and they have to be

18   manually released, correct?

19   A.   Yes, yes, yes.

20   Q.   Now, let's look at third

21   item on this page. It reads, "Current BW

22   report algorithm measures orders by NDC

23   number, SKU, not drug class, total

24   fentanyl, for example, or consolidated

```
 1    customer, just ship-to address, and total

 2    brand base of controlled substance to the

 3    consolidated or individual registrant."

 4              Okay.  Now, this is the

 5    potential issue and enhancement that

 6    Mr. Janush spent a lot of time talking to

 7    you about in this deposition, correct?

 8         A.    Yes.

 9         Q.    Okay.  And previously you

10    tried to explain to him what the issue

11    was.

12              Let's look at your comment

13    over on the right-hand side.

14              MR. JANUSH:  Object to the

15         narrative.

16              MR. BARKER:  Okay.  We'll

17         strike the narrative.

18    BY MR. BARKER:

19         Q.    I want to -- on this topic,

20    I want to direct your attention to the

21    comment SB-4.  Who is making this

22    comment?

23         A.    Brian Strehlke.

24         Q.    And Brian Strehlke works
```

Highly Confidential - Subject to Further Confidentiality Review

1   with you, correct?

2   A.   Yes, yes.

3   Q.   And what does Mr. Strehlke

4   say?

5   A.   "Considering drug class and

6   customer locations should go a long way

7   towards eliminating false positives in

8   the report."

9   Q.   Okay. And what's he talking

10   about there?

11   A.   He's talking about when we

12   had -- as I explained earlier today, if a

13   customer only orders one SKU once a year,

14   when it's time for them to reorder, they

15   automatically come up as a flagged order

16   and per our process, we have to

17   investigate, document the investigation,

18   and then -- prior to releasing it.

19   Q.   And right below

20   Mr. Strehlke's comment is another comment

21   from you. That's DM, right?

22   A.   Yes.

23   Q.   And what's your comment?

24   A.   "Agree, can't tell you how

1   many investigations are done because a

2   customer hasn't ordered a particular

3   strength in the last 12 months."

4   Q.   Okay.   And is this what you

5   were trying to explain to Mr. Janush

6   before, that the improvement of moving

7   from a SKU-based system to a brand-based

8   system would reduce the number of

9   potentially questionable orders that you

10   had to investigate?

11   MR. JANUSH: Objection.

12   THE WITNESS: It would

13   eliminate the false positives so

14   that the orders that we do see

15   would be the ones that are truly

16   suspicious and not based on the

17   ordering pattern of the customer.

18   BY MR. BARKER:

19   Q.   Well, you mean truly

20   potentially suspicious, correct?

21   A.   Right.

22   Q.   Because until you complete

23   your investigation, you don't know

24   whether they are suspicious?

1   A.   Agreed.

2   Q.   Were any of the improvements

3   that were being discussed at this meeting

4   or in Mr. Woodworth's report from the

5   group DCAG about improving the system so

6   that you would catch orders that were

7   potentially suspicious that were possibly

8   being missed?

9   A.   No.

10   Q.   Okay. Were there additional

11   updates to Janssen's suspicious order

12   monitoring program in 2017 and 2018?

13   A.   Well, after receiving the

14   recommendations from DCAG we did

15   implement some changes to address some of

16   the recommendations enhancing our

17   program. So there were SOP changes, an

18   introduction of a customer form to fill

19   out when we do have questionable orders.

20   Q.   Okay. And let's talk about

21   Mr. Woodworth, right?

22   A.   Yes.

23   Q.   Were you the one that hired

24   Mr. Woodworth and his group, the Drug and

1   Chemical Advisory Group?

2   A.   I was involved with the

3   selection of him, to bring him in, yes.

4   Q.   Was -- and if I refer to

5   that as DCAG for short, would you

6   recognize that as the Drug and Chemical

7   Advisory Group?

8   A.   Drug and Chemical

9   Advisory -- yes.

10   Q.   Were you familiar with the

11   drug and chemical advisory group?

12   A.   Yes.

13   Q.   I'm going to hand you a

14   document that we marked as Exhibit 55

15   which are the bios of the DCAG principals

16   that were pulled off of their website.

17   (Document marked for

18   identification as Exhibit

19   Janssen-Dempsey-55.)

20   BY MR. BARKER:

21   Q.   You testified before that

22   you knew about DCAG before you hired

23   them?

24   A.   Yes.

 1   Q.   And how -- how do you know

 2   the principals of DCAG?

 3   A.   When I was working for

 4   Noramco, I know that Terry Woodworth and

 5   Frank Sapienza had provided guidance to

 6   the Noramco company. So that's how I

 7   knew them.

 8   Q.   Okay. And their bios are

 9   briefly stated on the second page of

10   Exhibit 55, correct?

11   A.   Well, Frank Sapienza starts

12   on the bottom of the first page.

13   Q.   It does. You're absolutely

14   right, even though his picture is on the

15   next page. It starts -- starts here.

16   And did you review their

17   qualifications before you hired them?

18   A.   For suspicious order

19   monitoring, no.

20   Q.   But did you have an

21   understanding as to whether either of

22   them had a background with the DEA

23   before --

24   A.   Yes.

Highly Confidential - Subject to Further Confidentiality Review

```
 1            Q.    -- you hired them?

 2            A.    Yes.  I knew from my

 3    experience at Noramco that they were

 4    retired headquarter DEA employees with

 5    experience and knowledge of the

 6    regulations.

 7            Q.    Okay.  And, in fact,

 8    Mr. Sapienza was a former chief of the

 9    drug and chemical evaluation section of

10    the DEA office of diversion control,

11    correct?

12            A.    Yes.

13            Q.    And Mr. -- Mr. Woodworth was

14    deputy director in the DEA office of

15    diversion control, correct?

16            A.    Yes.

17            Q.    You thought that these

18    gentlemen would be knowledgeable about

19    diversion issues and suspicious order

20    monitoring, correct?

21                  MR. JANUSH:  Objection.

22                  THE WITNESS:  Yes.

23    BY MR. BARKER:

24            Q.    Let's talk about the report
```

Highly Confidential - Subject to Further Confidentiality Review

```
 1    that was generated by the DCAG group.

 2                    MR. JANUSH:  Which one?

 3                    MR. BARKER:  That's not --

 4          there were multiple -- was that an

 5          objection, sir?

 6                    MR. JANUSH:  I'm asking

 7          which one so that I know which

 8          ones to pull up.

 9                    MR. BARKER:  You'll know

10          when I give you an exhibit number.

11                    MR. JANUSH:  All right.

12    BY MR. BARKER:

13          Q.    If you pull out from your

14    stack of exhibits over there from earlier

15    today, pull out Exhibit 26.  Do you have

16    Exhibit 26 in front of you?

17          A.    I do.

18          Q.    We previously went over

19    that.  This was the initial draft of the

20    report provided by Mr. Woodworth --

21    Woodworth, excuse me, correct?

22          A.    Correct.

23          Q.    And I want you to turn to

24    Page 2, and direct your attention to the
```

1   full paragraph at the bottom.

2   A.   Yes.

3   Q.   And what was DCAG's ultimate

4   conclusion about Janssen's suspicious

5   order monitoring system, in the initial

6   draft of its report?

7   A.   The DCAG evaluation found

8   that the suspicious orders monitoring

9   program for the JOM site in

10   Shepherdsville, Kentucky complies with

11   the DEA requirements set forth in the

12   federal regulations, Title 21 Code of

13   Federal Regulations, C.F.R. section

14   1301.74(b).

15   Q.   And those were sections of

16   the C.F.R. that Mr. Janush showed you

17   repeatedly talking about orders of

18   unusual size, unusual frequency or an

19   unusual pattern, correct?

20   A.   That is the section that

21   says you need to have a -- design and

22   operate a system to disclose orders --

23   Q.   Or to identify suspicious

24   order monitoring.

1   BY MR. JANUSH:

2   Q.   Opioid products aren't --

3   we're not talking about a standard

4   prescription that's a non-opioid drug,

5   are we?

6   MR. BARKER: Object to form.

7   THE WITNESS: Can you repeat

8   what you're trying to say?

9   Because we are monitoring

10   Duragesic, and we are also

11   monitoring Concerta, which isn't

12   an opiate. We're also monitoring

13   the Nucynta. And I'm trying to

14   understand what you're saying,

15   because the suspicious order

16   monitoring program is a system.

17   It's not just an algorithm.

18   So whether the algorithm is

19   flagging all three or your overall

20   program is encompassing all

21   three --

22   BY MR. JANUSH:

23   Q.   But you don't get to the

24   overall program unless the algorithm

Highly Confidential - Subject to Further Confidentiality Review

1   flags the order to begin with. I'm

2   talking about in real time, as you

3   testified earlier today with me, you

4   don't get to a suspicious order review

5   unless the algorithm flags a particular

6   order initially?

7   A.   For the particular order,

8   but we do look at the entire order

9   shipped to that customer.

10   Q.   But you do that as like a

11   monthly meeting, right?

12   A.   But it's still looking at

13   what where we've distributed to the

14   customer --

15   Q.   But it's too --

16   A.   -- on a whole.

17   Q.   When you've done the monthly

18   meeting, you've already shipped the

19   product, right?

20   A.   Yes, but if there was an

21   order that was not typical, there had

22   been an investigation.

23   Q.   But again, not typical is

24   viewed against -- not typical is viewed

Highly Confidential - Subject to Further Confidentiality Review

1   against your initial algorithm, is what

2   flags what's not typical, right?

3   MR. BARKER: Object to form.

4   BY MR. JANUSH:

5   Q.   Day one, realtime, shipping

6   an order, it's your algorithm that flags

7   the order, right?

8   MR. BARKER: Object to form.

9   THE WITNESS: Not

10   necessarily, because if we know

11   that there's a change downstream,

12   the customer has gotten a new

13   contract, we know in advance that

14   there's going to be an uptick in

15   demand. And before the order is

16   placed -- for example, when we

17   reviewed with Kentucky DEA,

18   because of the opioid tax, we were

19   asked to ship directly to New

20   York.

21   So we knew that we had no

22   history going to New York. So no,

23   the order system did not flag,

24   because we knew in advance that we

Highly Confidential - Subject to Further Confidentiality Review

1   were shipping to New York State

2   with no history. And we had to do

3   an investigation to figure out how

4   much typically goes to New York

5   prior to the order.

6   So you are just focused on

7   the algorithm. But I'm saying our

8   overall suspicious order

9   monitoring program, there's other

10   components to it.

11   BY MR. JANUSH:

12   Q.   Those other components,

13   though, don't typically come into play in

14   the regular course of business when you

15   have rolling customers who are known to

16   you. We're not talking about the rare

17   issue of the opioid tax, and having a

18   base level of knowledge of zero, and

19   having to investigate on the front end.

20   With a customer that is known to you and

21   has been purchasing from you, your

22   algorithm is the trigger to start an

23   investigation, true or false?

24   MR. BARKER: Object to form.

Highly Confidential - Subject to Further Confidentiality Review

```
 1                    THE WITNESS:  For our

 2          established products, we place the

 3          order.  We know when the customer

 4          orders because they -- the big

 5          three have their days when they

 6          place the orders.  We know what

 7          they historically order.  And if

 8          there is an increase, the

 9          algorithm does tell us if there is

10          an atypical ordering pattern.

11     BY MR. JANUSH:

12          Q.    My question was, with a

13     customer that is known to you and has

14     been purchasing from you, your algorithm

15     is the trigger to start an investigation,

16     true or false?

17                    MR. BARKER:  Object to form.

18                    THE WITNESS:  And I'm saying

19          in the typical business, yes, an

20          order goes through the algorithm,

21          and it's reviewed.  And if it

22          comes up as flagged, we

23          investigate.  But there are orders

24          that we know in advance that are
```

Highly Confidential - Subject to Further Confidentiality Review

1   called "Recommendations"?

2   A.   It doesn't say conclusion.

3   That's recommendation.

4   Q.   It's a heck of a lot

5   stronger than executive summary?

6   THE WITNESS: It doesn't say

7   conclusion.

8   MR. BARKER: Object to form.

9   THE WITNESS: It says

10   recommendations.

11   BY MR. JANUSH:

12   Q.   I honestly can't believe

13   you're fighting with me over that word.

14   A.   It is --

15   MR. BARKER: I can't believe

16   that you're arguing with the

17   witness over something that

18   doesn't say conclusions. It says

19   recommendations.

20   MR. JANUSH: Right.

21   Recommendations.

22   MR. BARKER: Future actions,

23   not past.

24   MR. JANUSH: Excuse me.

Highly Confidential - Subject to Further Confidentiality Review

1   Excuse me.

2   MR. BARKER: Well, you're

3   arguing with the witness. So I'm

4   arguing with you.

5   MR. JANUSH: So move to

6   strike counsel's interruptions.

7   BY MR. JANUSH:

8   Q.   I'm talking to you. You're

9   my witness. I'm going to ask you some

10   questions about recommendations.

11   You hired an auditor to make

12   recommendations to improve your system,

13   right?

14   A.   We hired an auditor to give

15   us recommendations to enhance our current

16   program so that we could be proactive.

17   Q.   That's a long way of saying

18   right, isn't it?

19   A.   These aren't improvements.

20   These are recommendations. He said we're

21   compliant. These are recommendations to

22   make it better, enhancements.

23   MR. JANUSH: Move to strike.

24   Nonresponsive.

1   MR. BARKER: Object to the

2   objection. It's --

3   MR. JANUSH: Enough.

4   MR. BARKER: -- commentary.

5   BY MR. JANUSH:

6   Q.   Let's go to Page 10. At

7   Recommendation 4, he told you to start

8   modifying the existing suspicious order

9   monitoring algorithm and/or adding

10   algorithms to include additional

11   evaluation criteria for each specific DEA

12   basic class of controlled substance

13   handled by J&J; example, fentanyl,

14   methylphenidate, tramadol. Right?

15   MR. BARKER: Object to form.

16   THE WITNESS: Right.

17   BY MR. JANUSH:

18   Q.   He told you to consider a

19   base unit of measurement, such as grams

20   of active ingredient, for the SOM

21   algorithms, right?

22   A.   Yes.

23   Q.   Are you following that

24   instruction going forward, by the way?

 1   A.   As a matter of fact, today

 2   we are receiving thresholds from The

 3   Analysis Group on a new product that will

 4   be grams for our esketamine product.

 5   Q.   And a gram-based unit of

 6   measurement for a suspicious order

 7   monitoring program is more rigorous than

 8   the program you've had in place for the

 9   last many years, isn't it?

10   MR. BARKER: Object to form.

11   THE WITNESS: I can't answer

12   that question because, in talking

13   to Analysis Group, we are going to

14   be most likely -- we won't be

15   getting the orders that we

16   received that the -- the false

17   positives. So I cannot say

18   whether going to this is going to

19   give us fewer or more orders,

20   because we are launching a new

21   product, so we're going to be

22   receiving a higher number of

23   orders. So I can't give you an

24   answer right now if this is going

Highly Confidential - Subject to Further Confidentiality Review

1   to be less or more.

2   BY MR. JANUSH:

3   Q.   I didn't say less or more.

4   I said more rigorous. And I'm talking

5   about spotting actual suspicious orders.

6   A.   That is the intent of going

7   to this, the intent.

8   Q.   Right. We're not talking

9   about -- I'm not here to talk about false

10   positives. This case, this opioid

11   epidemic, isn't about false positives.

12   It's about real orders that made it out

13   there that shouldn't have made it out

14   there.

15   Do you understand that?

16   MR. BARKER: Object to form.

17   THE WITNESS: I understand

18   you.

19   BY MR. JANUSH:

20   Q.   Okay. Now, I understand

21   that you want to talk about false

22   positives. I want to talk about what

23   Terrance was seeking to do in this audit

24   and in this recommendations. Okay?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   Okay.

2   Q.   Next, he said, "Consider

3   separating J&J customers into two or more

4   groups and perform different analyses of

5   orders for these different groups;

6   largest three wholesalers in one group,

7   smaller wholesalers in another group."

8   Do you see that?

9   A.   Yes.

10   Q.   Are you following something

11   like that going forward in your new

12   program?

13   A.   Yes, we are.

14   Q.   When he said, "Consider

15   evaluating customer orders for specific

16   DEA basic classes of substances against

17   similar size and geographically placed

18   customers and perform national, regional,

19   state, and perhaps three digit zip code

20   comparisons among like-size customers."

21   Did I read that right?

22   A.   Yes, you did read it.

23   Q.   Are you implementing any of

24   that in your new protocols?

Highly Confidential - Subject to Further Confidentiality Review

1   A.   You saw the IntegriChain

2   statement of work, so yes, we are going

3   to be going to that level.

4   Q.   Okay. And now, at 4-A,

5   Terrance advised, "Stop using this

6   current single-criterion algorithm which

7   selects and holds orders from customers

8   when the quantity of an order is greater

9   than three times, 300 percent, the

10   customer's average weekly order based on

11   a rolling 12-month ordering history from

12   that customer."

13   Did I read that right?

14   A.   Yes.

15   Q.   And he said, "This algorithm

16   only measures quantity and does not

17   consider frequency or a pattern of

18   ordering by the same customer."

19   Did I read that right?

20   A.   Yes, you did.

21   Q.   That statement isn't about

22   limiting Janssen's or JOM's false

23   positives. That statement is about

24   improving your program so that you

Highly Confidential - Subject to Further Confidentiality Review

1   measure the other two C.F.R.-required

2   elements, isn't it?

3   MR. BARKER: Object to form.

4   THE WITNESS: In our

5   algorithm, he is suggesting that

6   we capture all three.

7   BY MR. JANUSH:

8   Q.   My question was, that

9   statement isn't about limiting Janssen's

10   or JOM's false positives. That statement

11   is about improving your program so you

12   measure the other two C.F.R.-required

13   elements, isn't it?

14   MR. BARKER: Object to form.

15   THE WITNESS: He is

16   suggesting that we make

17   enhancements to the algorithm to

18   capture more formally the

19   frequency and pattern requirements

20   that we are doing outside --

21   BY MR. JANUSH:

22   Q.   Because --

23   A.   -- of the algorithm.

24   Q.   Because there's a risk that

Highly Confidential - Subject to Further Confidentiality Review

1   if you don't have those elements in your

2   algorithm, those elements are possibly

3   being missed, right?

4   MR. BARKER: Object to form.

5   THE WITNESS: Not with our

6   current products, because we have

7   established customers that haven't

8   changed that much, and we know

9   what they're ordering. This

10   report was not just for

11   established products, but for this

12   product that just got approval

13   this year. And we will have more

14   customers, different distribution,

15   and more orders.

16   So he's saying, make sure

17   that we need to make these

18   changes.

19   BY MR. JANUSH:

20   Q.   You bring up a really good

21   point. Thank you so much.

22   The point that you're

23   bringing up is, you had a one-dimensional

24   algorithm during the hottest years that

Highly Confidential - Subject to Further Confidentiality Review

```
 1    were you selling Duragesic and Nucynta;

 2    isn't that right?

 3                 MR. BARKER:  Object to form.

 4                 THE WITNESS:  What were the

 5         hottest years?

 6    BY MR. JANUSH:

 7         Q.    Well, Nucynta came on the

 8    market in 2009.  Nucynta was divested, I

 9    believe, in 2015 or '16.

10         A.    When you mean the hottest

11    years --

12         Q.    So meaning, when Terrance is

13    doing this review, it's already long

14    after Nucynta is gone, right?

15                 MR. BARKER:  Object to form.

16                 THE WITNESS:  Nucynta was

17         gone.

18    BY MR. JANUSH:

19         Q.    And you had a

20    one-dimensional algorithm during the

21    entire time Nucynta was being sold,

22    right?

23                 MR. BARKER:  Object to form.

24                 THE WITNESS:  We had an
```

Highly Confidential - Subject to Further Confidentiality Review

```
 1              algorithm that looked at the

 2              quantity that the customer -- the

 3              historical ordering pattern.

 4    BY MR. JANUSH:

 5         Q.    And that is a

 6    one-dimensional algorithm, right?

 7              MR. BARKER:  Object to form.

 8              THE WITNESS:  The algorithm

 9         had one factor.

10    BY MR. JANUSH:

11         Q.    As you sit here today, and

12    after reading Terrance's report from the

13    Drug and Chemical Advisory Group, you're

14    not the least bit concerned that during

15    the years that you were selling the

16    opioid product, Nucynta, and during the

17    heavier years, before it became generic,

18    that you were selling and marketing

19    Duragesic, that you only had a

20    one-dimensional, one-factor algorithm?

21              MR. BARKER:  Object to form.

22              THE WITNESS:  If there was a

23         problem with our products, we

24         would have been called down as
```

Highly Confidential - Subject to Further Confidentiality Review

1   part of the distributor

2   initiative.

3   BY MR. JANUSH:

4   Q.   That's not what I asked you.

5   A.   No.   You're asking if we

6   were concerned.   And that would mean, I

7   would be concerned if there was diversion

8   and abuse of our products.   And if there

9   was, that was one of the criteria for the

10   distributor initiative.   You were called

11   in, reviewed your SOM and your ARCOS

12   data.

13   Q.   And two of the other

14   requirements of the C.F.R. at the very

15   same time as the distributor initiative

16   was ongoing concerned the fact that you

17   were to be measuring frequency as well as

18   ordering patterns, not just quantity;

19   isn't that right?

20   A.   The C.F.R. says you need to

21   have a system in place.   It does not say

22   your algorithm is the system.

23   Q.   But if your algorithm isn't

24   measuring all three factors, you cannot

Highly Confidential - Subject to Further Confidentiality Review

1   trigger for all three factors to be

2   reviewed. It would require a manual

3   review of every single order for you to

4   have a good system in the absence of

5   those two factors; isn't that right?

6   MR. BARKER: Object to form.

7   THE WITNESS: For Schedule

8   II orders, they are manually

9   entered. We get them on the same

10   days every week. The customer

11   service personnel know what the

12   customers typically order.

13   And when it goes in, the

14   algorithm would flag anything

15   suspicious, if the customer

16   service -- they're seeing every

17   Monday, Wednesday, from this

18   customer. This one only receives

19   once every 12 months.

20   BY MR. JANUSH:

21   Q.   You're not saying customer

22   service is eyeballing every order and

23   manually checking every order, are you?

24   A.   No. What I'm saying

1   overall, there is a program in place

2   where orders are looked at, and every

3   month we reviewed the orders that were

4   reviewed, put on, and we track how much

5   is going to all the customers based on

6   total controlled versus noncontrolled.

7   Q.   But you weren't following

8   the C.F.R. --

9   A.   The C.F.R. does not say your

10   algorithm needs to have all this.

11   Q.   But your algorithm is what

12   triggers the review, right?

13   A.   I'm saying we do other

14   reviews of all the other --

15   Q.   You can't review an order

16   that wasn't tripped, correct? You can't

17   review it in realtime is what I'm saying?

18   If it's not tripped, it ships, right?

19   MR. BARKER: Object to form.

20   THE WITNESS: If it is not

21   typical of the ordering pattern

22   for the previous 12-month, 52-week

23   average, we --

24

Highly Confidential - Subject to Further Confidentiality Review

```
 1    BY MR. JANUSH:

 2         Q.    Ship it?

 3              MR. BARKER:  Object to form.

 4              THE WITNESS:  No.  We

 5         investigate.

 6    BY MR. JANUSH:

 7         Q.    If it's -- if -- I'm saying

 8    if you have an order and you're only

 9    investigating an order on an algorithm

10    that measures quantity, you inherently

11    cannot trip that order via the algorithm

12    for frequency or for --

13         A.    You can do pattern.

14         Q.    -- pattern?

15         A.    You can do pattern, because

16    if they don't order on a monthly basis

17    it's going to get flagged.  That's a

18    pattern.

19         Q.    When you say if they don't

20    order on a monthly basis.  That's more

21    like when a SKU is not ordered over a

22    period of time, it trips?

23         A.    So if a customer regularly

24    orders every month 100 each of a product,
```

1   that is their order. Their average is

2   going to be factored on that. So if they

3   deviate and all of the sudden orders 150,

4   it's going to flag it, that the quantity

5   is high, and then when we run the report,

6   we'll say, well, hey, why -- you've

7   always been getting 100 each. Why are

8   you asking 150 this month?

9   Q.   Right. But that's a

10   quantity measurement. That's --

11   A.   But that's also the pattern,

12   because the pattern takes in the

13   12 months, what they typically order, to

14   come up with the average.

15   Q.   Right. The 12 months in

16   average, 150 is not going to be an

17   outlier on an average on -- if an order

18   is 100 for 12 months, you're going to

19   average that in, that's not going to be

20   a -- that's going to be a blip on the

21   radar, is what your example is.

22   A.   I used the wrong number.

23   But if it -- if it was a significant

24   increase, it would have been.

1   Q.   And then Terrance goes on to

2   say, going back to his recommendations,

3   "The algorithm would not detect multiple

4   customer orders during a given week. It

5   would not detect orders which consist of

6   gradual quantity increases of a

7   controlled substance over time."

8   Do you agree with his

9   position that the algorithm that you had

10   wouldn't have detected multiple customer

11   orders during a given week?

12   A.   If we received multiple on

13   days that we weren't expecting.

14   Q.   I'm not -- I'm not --

15   A.   Because --

16   Q.   -- allowing you to add --

17   add language on days that you were not

18   expecting. I'm talking about what he's

19   addressing.

20   He's addressing, "The

21   algorithm would not detect multiple

22   customer orders during a given week."

23   MR. BARKER: Object to form.

24

```
 1    BY MR. JANUSH:

 2         Q.    Do you agree that the

 3    algorithm would not have addressed

 4    multiple customer orders during a given

 5    week?

 6                   MR. BARKER:  Object to form.

 7                   THE WITNESS:  That is what

 8         he wrote, and if they ordered it

 9         continuously every single day, it

10         compares to the previous weeks.

11    BY MR. JANUSH:

12         Q.    Or even multiple orders in a

13    week like I showed earlier with Cardinal,

14    right?

15                   MS. BOODY:  Object to form.

16    BY MR. JANUSH:

17         Q.    It compares it to the

18    previous weeks, right?

19                   MR. BARKER:  Object to form.

20                   THE WITNESS:  That is

21         comparing to the previous weeks

22         average, the 52 weeks.

23    BY MR. JANUSH:

24         Q.    So if Cardinal ordered every
```

 1   three days a specific order, what

 2   Terrance is saying is, your algorithm is

 3   not detecting multiple customer orders

 4   during a given week.

 5   A.   That is what he's saying.

 6   Q.   Do you disagree with it or

 7   agree with it?

 8   A.   I don't know. Because I

 9   would have to see somebody actually go --

10   we never had the case where somebody's

11   going in every single day to see what the

12   algorithm would do.

13   Q.   And then he wrote, "It would

14   not detect orders which consist of

15   gradual quantity increases of a

16   controlled substance over time."

17   Do you see that?

18   A.   Yes.

19   Q.   Do you agree or disagree

20   with that statement?

21   A.   I agree.

22   Q.   And he wrote, "It would not

23   detect a new customer's orders for

24   controlled substances which initially

Highly Confidential - Subject to Further Confidentiality Review

1   commence with larger than normal

2   quantities and remain at a constant

3   level."

4   Do you agree or disagree

5   with that recommendation?

6   A.   If it was entered in

7   initially at a high level, yes.

8   Q.   And he wrote that, "Your

9   algorithm does not distinguish between

10   controlled substances."

11   Do you agree that?

12   A.   What do you think -- we

13   treat all of our control -- the

14   algorithm, we use it for -- no matter

15   what schedule, if it's an ADHD med or if

16   it's an opioid.

17   Q.   I think that's his point,

18   that he's recommending that that be

19   modified. Isn't that his point?

20   MR. BARKER: Object to form.

21   THE WITNESS: I don't know

22   what he intended.

23   BY MR. JANUSH:

24   Q.   Well, go up to Paragraph 4.

1   Isn't the purpose of Paragraph 4, above,

2   "Start modifying the existing SOM

3   algorithm and/or adding algorithms to

4   include additional evaluation criteria

5   for each specific DEA basic class of

6   controlled substance handled by J&J."

7   Isn't that going to this

8   concept of distinguishing between

9   controlled substances?

10   A.   I misread this in thinking

11   that the algorithm doesn't do anything

12   different, no matter what the product is,

13   whether it's an opiate or a psychotropic.

14   And what he was saying is you should lump

15   in all the SKU -- all the total quantity

16   of the drug class and -- rather than the

17   SKU.

18   Q.   Right. That's a critique on

19   his part, isn't it? I mean, I'm going to

20   find out. I'm going to be deposing him

21   one day. So I just want your opinion

22   whether he's critiquing Janssen or not on

23   this.

24   MR. BARKER: Object to form.

1   THE WITNESS: I don't know

2   what he means by that.

3 BY MR. JANUSH:

4   Q.   Even when you look up at

5 Paragraph 4, you --

6   A.   Well, I understand what he's

7 saying up here, that we should move from

8 the SKU to do an overall -- the drug

9 class of that product.

10   But down here, the algorithm

11 doesn't -- I don't know if he's saying,

12 you should do something different from

13 opiates versus ADHD. You shouldn't.

14 It's all a controlled substance.

15   Q.   So let's talk about -- let's

16 talk about what he's saying in Paragraph

17 4.

18   Earlier, I was just

19 following along the lines of what JOM has

20 done. I was only looking at, on that

21 sales spreadsheet, the 100-milligram,

22 bottles of 100 pills, packed in 24

23 bottles per case.

24   Do you remember that?

 1   A.   Yes.

 2   Q.   I wasn't also adding in the

 3   same day or same week orders for the

 4   Nucynta 50 milligrams or the Nucynta

 5   75 milligrams or the Nucynta

 6   125 milligrams on top of Cardinal's

 7   Nucynta 100-milligram orders.

 8   You agree I was not doing

 9   that, right?

10   MR. BARKER: Object to form.

11   MS. BOODY: Object to form.

12   THE WITNESS: You were just

13   highlighting the 100-milligram.

14   BY MR. JANUSH:

15   Q.   Right. So there is a reason

16   I'm circling back to that, because what

17   Terrance was suggesting, was to move away

18   from the SKU to SKU, the same SKU

19   analysis, and lump in the total grams of

20   product and take into account all of the

21   Nucynta that would have been ordered by,

22   as an example, Cardinal, in a given week

23   or month, right?

24   A.   Right.

Highly Confidential - Subject to Further Confidentiality Review

1   Q.   And there is a huge

2   difference between that suspicious order

3   monitoring analysis, and just going SKU

4   to SKU, isn't there?

5   MR. BARKER: Object to form.

6   THE WITNESS: It depends,

7   because when you come down to it,

8   and you just calculate how much

9   active ingredient is in a

10   50-milligram -- so there's

11   50 milligrams times 100 pills,

12   times whatever you mention, you're

13   going to come up with a different

14   historical ordering pattern.

15   And so you are not going to

16   have more flagged orders than we

17   currently have.

18   BY MR. JANUSH:

19   Q.   Well, you're going to

20   have -- you're not going to have the

21   false positives on the company that

22   ordered a lot of the 100s of Nucynta but

23   may have only ordered a few of the 50s,

24   and then increases their orders of 50,